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**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF NEW YORK**

20 | Ashley America,

Plaintiff,

V.

MERCK & CO., INC., a New Jersey Corporation;  
and MERCK SHARP & DOHME CORP., a New Jersey Corporation.

### Defendants.

Case No. 6:22-CV-1049 (FJS/ML)

## **COMPLAINT FOR**

- (1) Negligence
- (2) Strict Liability (Failure to Warn)
- (3) Strict Liability (Manufacturing Defect)
- (4) Breach of Warranty
- (5) Common Law Fraud

**DEMAND FOR JURY TRIAL**

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1 COMES NOW Plaintiff, ASHLEY AMERICA, who, by and through her counsel, alleges  
2 against defendants MERCK & CO., INC., and MERCK, SHARP AND DOHME CORPORATION,  
3 and each of them, as follows:

4 **INTRODUCTION**

5 1. This common-law products liability, negligence, strict liability, breach of warranty and  
6 fraud action arises out of serious and debilitating injuries, including but not limited to non-epileptic  
7 seizures, likely related to autoimmune dysregulation, syncope, related to dysregulation of the  
8 autonomic nervous system, and chronic fatigue syndrome, Neurocardiogenic with resulting sequelae  
9 that Plaintiff, Ashley America (“Plaintiff”), sustained as a result of receiving the Gardasil vaccine,  
10 which was manufactured, labeled, and promoted by defendants Merck & Co., Inc., and Merck, Sharp  
11 and Dohme Corporation (collectively “Merck”).

12 **PARTIES AND VENUE**

13 2. Plaintiff, Ashley America (“America” or “Plaintiff”), is a resident and citizen of New  
14 York.

15 3. Defendant Merck & Co., Inc., is a New Jersey corporation with its principal place of  
16 business at One Merck Drive, Whitehouse Station, New Jersey.

17 4. Defendant Merck, Sharp and Dohme Corporation, is a New Jersey corporation with its  
18 principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

19 5. Defendants Merck & Co., Inc., and Merck, Sharp and Dohme Corporation shall  
20 hereinafter collectively be referred to as “Merck” or “Defendant(s).”

21 6. At all times herein mentioned, each Defendant was the agent, servant, partner, aider and  
22 abettor, co-conspirator and/or joint venturer of the other Defendants named herein and was at all times  
23 operating and acting within the purpose and scope of said agency, service, employment, partnership,  
24 conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other  
25 defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

26 7. At all times herein mentioned, Defendants were fully informed of the actions of their  
27 agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated  
28 those actions, which failure to repudiate constituted adoption and approval of said actions and all

1 defendants and each of them, thereby ratified those actions.

2       8.     There exists and, at all times herein mentioned there existed, a unity of interest in  
3 ownership between the named Defendants, such that any individuality and separateness between the  
4 defendants has ceased and these Defendants are the alter-ego of each other and exerted control over  
5 each other. Adherence to the fiction of the separate existence of these two named Defendants as  
6 entities distinct from each other will permit an abuse of the corporate privilege and would sanction a  
7 fraud and/or would promote injustice.

8       9.     At all times herein mentioned, the two Merck Defendants were engaged in the business  
9 of, or were successors in interest to, entities engaged in the business of researching, formulating,  
10 compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing,  
11 marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling  
12 products for use by patients such as Plaintiff, her parents and her medical providers. As such, the two  
13 Merck Defendants are each individually, as well as jointly and severally, liable to Plaintiff for her  
14 damages.

15      10.    The harm caused to Plaintiff resulted from the conduct of one or various combinations  
16 of the two Merck Defendants, and through no fault of Plaintiff. There may be uncertainty as to which  
17 one or which combination of the two Merck Defendants caused the harm. The two Merck Defendants  
18 have superior knowledge and information on the subject of which one or which combination of the  
19 two Defendants caused Plaintiff's injuries. Thus, the burden of proof should be upon each of the two  
20 Merck Defendants to prove that the Defendant has not caused the harms Plaintiff has suffered. As  
21 previously stated, the two named Merck Defendants shall hereinafter and throughout this Complaint  
22 be collectively referred to as "Merck" or "Defendant(s)."

23      11.    Merck is the manufacturer, labeler and promoter of the Gardasil and Gardasil-9  
24 vaccines, which are purported to be "cervical cancer vaccines" by preventing a handful of the  
25 hundreds of strains of the Human Papillomavirus ("HPV"). Merck regularly conducts and transacts  
26 business in Florida and has promoted Gardasil to consumers, patients, hospitals, physicians, nurses  
27 and medical professionals, including but not limited to Plaintiff, her parents and the medical facility  
28 and medical professionals who prescribed and/or injected Plaintiff with Gardasil. This Court has

1 personal jurisdiction over Merck because Defendants have sufficient minimum contacts with New  
2 York to render the exercise of jurisdiction by this Court proper.

3       12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.  
4 §1332(a) because Plaintiff and Defendants are citizens of different states, and the amount of  
5 controversy exceeds \$75,000.00, exclusive of interest and costs.

6       13.   Venue is proper in this Court pursuant to 28 U.S.C. §1331 because a substantial portion  
7 of the events and omissions giving rise to the claims asserted herein occurred in this District.

## **GENERAL ALLEGATIONS**

## I. “History Doesn’t Repeat Itself, But It Often Rhymes” – Mark Twain

14. Merck traces its history back to 1668, when the original founder of the company, Friedrich Jacob Merck, bought an apothecary in Darmstadt, Germany. The company operated as a pharmacy for approximately the next 150+ years when, in 1827, Friedrich's descendant, Heinrich Emmanuel Merck, converted the company into a drug manufacturing enterprise. Merck's first products included morphine and cocaine.

15        15. Merck later manufactured a number of controversial products including Fosamax (a  
16 purported bone density drug that caused bone fractures), Nuvaring (a birth control device associated  
17 with life-threatening blood clots and death), and probably its most infamous drug, Vioxx (a pain  
18 medication Merck was forced to pull from the market due to its cardiovascular risks), all of which  
19 landed Merck in litigation hot water.

16. With regard to Vioxx, Merck was sued by tens of thousands of patients who alleged  
they suffered heart attacks and other cardiovascular injuries as a result of ingesting the blockbuster  
pain medication.

23        17. Documents unsealed during the Vioxx litigation in the early 2000s revealed a culture  
24 wherein Merck knew early on that Vioxx was linked to fatal cardiovascular adverse events but  
25 nonetheless intentionally chose to conceal these risks from the public and medical community and,  
26 instead, orchestrated a scheme to downplay the severity of the risks. Merck misrepresented the results  
27 of its clinical trials, failed to undertake the clinical trials that would reveal risks, and blacklisted  
28 medical professionals who dared to publicly criticize the safety of Vioxx. *See e.g.*, Eric J. Topol,

1 *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF  
2 MEDICINE 1707 (2004); Gregory D. Curfman et al., *Expression of Concern Reaffirmed*, 354 NEW  
3 ENGLAND JOURNAL OF MEDICINE 1193 (2006); Aaron S. Kesselheim et al., *Role of Litigation in*  
4 *Defining Drug Risks*, 17 JAMA 308 (2007); Harlan M. Krumholz et al., *What We Have Learnt From*  
5 *Vioxx*, 334 BRITISH MED. J. 120 (2007).

6       18. The British Medical Journal reported that internal documents and communications  
7 obtained from Merck during litigation revealed that Merck scientists internally acknowledged the  
8 existence of Vioxx's risks very early on: "Since the early development of [Vioxx], some scientists at  
9 Merck were concerned that the drug might adversely affect the cardiovascular system ... In internal  
10 emails made public through litigation, Merck officials sought to soften the academic authors'  
11 interpretation [of the data]. The academic authors changed the manuscript at Merck's request [to  
12 make less of the apparent risk] ..." Harlan M. Krumholz et al., *What We Have Learnt From Vioxx*,  
13 334 BRITISH MED. J. 120 (2007). And, despite Merck's knowledge of the risk, Merck never  
14 conducted the necessary studies designed to evaluate cardiovascular risk. *Id.*

15       19. In an article published in the Journal of the American Medical Association, it was  
16 reported that Merck worked to "diminish the impact of reported cardiovascular adverse effects by not  
17 publishing adverse events and failing to include complete data on myocardial infarctions that occurred  
18 during a key clinical trial. The information came to the public attention through a subpoena 5 years  
19 after the article's publication, when [Vioxx] was already off the market." Aaron S. Kesselheim et al.,  
20 *Role of Litigation in Defining Drug Risks*, 17 JAMA 308 (2007). The article concludes: "These case  
21 studies indicate that clinical trials and routine regulatory oversight as currently practiced often fail to  
22 uncover important adverse effects for widely marketed products. In each instance, the litigation  
23 process revealed new data on the incidence of adverse events, enabled reassessment of drug risks  
24 through better evaluation of data, and influenced corporate and regulatory behavior." *Id.*

25       20. It was also revealed and reported that, in order to control the public narrative that Vioxx  
26 was safe and risk free, "Merck issued a relentless series of publications...complemented by numerous  
27 papers in peer-reviewed medical literature by Merck employees and their consultants. The company  
28 sponsored countless continuing medical 'education' symposiums at national meetings in an effort to

1 debunk the concern about adverse cardiovascular effects.” Eric J. Topol, *Failing the Public Health –*  
2 *Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF MEDICINE 1707 (2004). In addition,  
3 Merck “selectively targeted doctors who raised questions about [Vioxx], going so far as pressuring  
4 some of them through department chairs.” Harlan M. Krumholz et al., *What We Have Learnt From*  
5 *Vioxx*, 334 BRITISH MED. J. 120 (2007). Dr. Topol, Chairman of the Department of Cardiovascular  
6 Medicine at the Cleveland Clinic, commented: “Sadly, it is clear to me that Merck’s commercial  
7 interest in [Vioxx] sales exceeded its concern about the drug’s potential cardiovascular toxicity.” Eric  
8 J. Topol, *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL  
9 OF MEDICINE 1707 (2004).

10       21. Once Merck’s misdeeds vis-à-vis Vioxx were revealed in various jury trials, Merck paid  
11 nearly \$5 billion to settle the tens of thousands of personal injury actions that had been brought  
12 against it as a result of its concealment of Vioxx’s cardiovascular risks. Merck paid an additional \$1  
13 billion to settle a securities class action brought by investors who had lost money when Merck’s stock  
14 tanked following revelations of the drug’s risks and subsequent lost sales. Merck was also forced to  
15 pay \$950 million in civil and criminal fines to the Department of Justice and other governmental  
16 entities as a result of various criminal activities Merck had engaged in with respect to Vioxx.

17       22. In 2005, Merck pulled Vioxx from the market and was desperate to find a replacement  
18 for its previous multi-billion-dollar blockbuster.

19       23. Merck viewed Gardasil as the answer to the financial woes it had suffered from Vioxx.  
20 Indeed, some have euphemistically noted that HPV stood for “Help Pay for Vioxx.”

21       24. In the aftermath of the Vioxx scandal, and seeking a replacement product, Merck’s  
22 senior director of clinical research, Eliav Barr, M.D., proclaimed of Gardasil: “This is it. *This is the*  
23 *Holy Grail!*”

24       **II. In Bringing Its *Holy Grail*, Gardasil, to Market, Merck Engaged in the Same**  
25 **Fraudulent Research and Marketing It Had Engaged in Vis-à-vis Vioxx Resulting**  
26 **In Patients Being Exposed to a Vaccine That is Of Questionable Efficacy, and**  
27 **Which Can Cause Serious and Debilitating Adverse Events**

28       25. As outlined herein, in researching, developing, and marketing its new Holy Grail,  
Gardasil, Merck engaged in the same unscrupulous tactics it had so infamously engaged in with

1 Vioxx.

2       26. Certain Merck employees, scientists and executives involved in the Vioxx scandal were  
3 also involved with Gardasil, and it appears they employed the very same methods of manipulating  
4 science and obscuring risks as they did with Vioxx.

5       27. According to Merck's marketing claims, Gardasil (and, later, next-generation Gardasil  
6 9) provided lifetime immunity to cervical and other HPV-associated cancers.

7       28. As discussed more fully below, whether Gardasil prevents cancer (not to mention  
8 lifetime immunity), is unproven. In fact, it may be more likely to cause cancer in those previously  
9 exposed to HPV than to prevent it.

10       29. Moreover, Merck knows and actively conceals the fact that Gardasil can cause a  
11 constellation of serious adverse reactions and gruesome diseases, including autoimmune diseases, and  
12 death in some recipients.

13       30. As a result of Merck's fraud, Gardasil today is wreaking havoc on a substantial swath of  
14 an entire generation of children and young adults on a worldwide scale.

15              **A. Overview of the Human Papillomavirus**

16       31. Human Papillomavirus ("HPV") is a viral infection that is passed between people  
17 through skin-to-skin contact. There are more than 200 strains of HPV, and of those, more than 40  
18 strains can be passed through sexual contact.

19       32. HPV is the most common sexually transmitted disease. It is so common that the  
20 majority of sexually active people will get it at some point in their lives, even if they have few sexual  
21 partners.

22       33. HPV, for the most part, is benign. More than 90 percent of HPV infections cause no  
23 clinical symptoms, are self-limited, and are removed from the human body by its own immunological  
24 mechanisms and disappear naturally from the body following an infection. *See, e.g., Antonio C. de*  
25 *Freitas et al., Susceptibility to cervical cancer: An Overview, 126 GYNECOLOGIC ONCOLOGY 306*  
26 *(August 2012).*

27       34. Approximately 12 to 18 of the over 200 strains of HPV are believed to be associated  
28 with cervical cancer and approximately six of the strains are believed to be associated with anal

1 cancer.

2       35. Not every HPV infection puts one at risk for cervical cancer. Only persistent HPV  
3 infections – not short-term or transient infections or sequential infections with different HPV types –  
4 in a limited number of cases with certain strains of the virus may cause the development of  
5 precancerous lesions. With respect to cervical cancer, these precancerous lesions are typically  
6 diagnosed through Pap smears and then removed through medical procedures. However, when  
7 undiagnosed, they may in some cases progress to cervical cancer in some women. Other risk factors,  
8 such as smoking, are also associated with cervical cancer. *See* Antonio C. de Freitas et al.,  
9 *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC ONCOLOGY 305 (August 2012).

10 Infection with certain types of HPV are also associated with other diseases, such as genital warts.

11       36. Public health officials have long recommended the Pap test (also known as Pap Smear),  
12 which detects abnormalities in cervical tissue, as the most effective frontline public health response to  
13 the disease.

14       37. Since its introduction, cervical cancer screening through the Pap test has reduced the  
15 rates of cervical cancer in developed countries by up to 80 percent. *Id.*

16       38. Incidences of cervical cancer have been declining dramatically worldwide as countries  
17 have implemented Pap screening programs.

18       39. New cases of cervical cancer in the U.S. affect approximately 0.8 percent of women in  
19 their lifetime. *See Cancer Stat Facts: Cervical Cancer*, NIH, at <https://seer.cancer.gov/statfacts/html/cervix.html>. For those who are diagnosed, cervical cancer is largely treatable, with a five-year  
20 survival rate of over 90 percent when the cancer is caught early. *See* Antonio C. de Freitas et al.,  
21 *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC ONCOLOGY 305 (August 2012).  
22 Anal cancer is even more rare, and according to the current data, approximately 0.2 percent of people  
23 will be diagnosed with anal cancer in their lifetime.

25       40. Although the incidence of cervical cancer was in rapid decline as a result of the  
26 implementation of routine testing and screening, including the Pap test and various DNA testing  
27 measures, Merck sought to fast-track a vaccine onto the market to prevent infection from four types of  
28 HPV (only two of which are associated with cancer).

1                   **B. Overview of the Gardasil Vaccine and Its Fast-Tracked Approval**

2         41. While there are over 200 types of the HPV virus, only 12 to 18 types currently are  
3 considered potentially associated with cervical or anal cancer. Merck's original Gardasil vaccine  
4 claimed to prevent infections from four strains (HPV Strain Types 6, 11, 16 and 18) and only two of  
5 those (Types 16 and 18) were associated with cervical and anal cancer.

6         42. Under Food and Drug Administration ("FDA") requirements, to obtain approval for  
7 marketing a vaccine, the manufacturer must conduct studies to test the effectiveness and safety of the  
8 vaccine. Once FDA approval is obtained, the manufacturer has a duty to perform any further  
9 scientific and medical investigation as a reasonably prudent manufacturer would perform, and to  
10 engage in any necessary post-marketing pharmacovigilance related to the product.

11         43. The FDA approved Gardasil on June 8, 2006, after granting Merck fast-track status and  
12 speeding the approval process to a six-month period, leaving unanswered material questions relating  
13 to its effectiveness and safety as well as when and to whom the Gardasil vaccine ought to be  
14 administered.

15         44. Merck failed, during the preapproval processing period and thereafter, to disclose (to  
16 the FDA and/or the public), material facts and information relating to the effectiveness and safety of  
17 Gardasil, as well as to whom the vaccine should or should not be administered.

18         45. Merck failed to perform in the preapproval processing period and thereafter, scientific  
19 and medical investigations and studies relating to the safety, effectiveness, and need for the Gardasil  
20 vaccine as either required by and under FDA directives and regulations, and/or those which a prudent  
21 manufacturer should have conducted unilaterally.

22         46. In June 2006, after the FDA's fast-tracked review, Gardasil was approved for use in  
23 females ages nine through 26 for the purported prevention of cervical cancer, and almost immediately  
24 thereafter, the Advisory Committee on Immunization Practices ("ACIP"), a committee within the  
25 Centers for Disease Control ("CDC"), recommended Gardasil for routine vaccination of adolescent  
26 girls ages 11 and 12 years old, but also allowed it to be administered to girls as young as nine years  
27 old.

28         47. On October 16, 2009, the FDA approved Gardasil for use in boys ages nine through 26

1 for the prevention of genital warts caused by HPV types 6 and 11, and in December 2010, it approved  
2 Gardasil for the purported prevention of anal cancer in males and females ages nine through 26.

3       48. Subsequently, Merck sought approval for Gardasil 9 (containing the same ingredients as  
4 Gardasil, but in higher quantities), which purportedly guarded against five additional HPV strains  
5 currently associated with cervical cancer and anal cancer (HPV Types 31, 33, 45, 52 and 58) than the  
6 original Gardasil, for a total of nine strains.

7       49. The FDA approved Gardasil 9 in December 2014 for use in girls ages nine through 26  
8 and boys ages nine through 15 for the purported prevention of cervical, vaginal, and anal cancers.

9 Presently, Gardasil 9 has been approved for and is being promoted by Merck to males and females  
10 who are between nine and 45 years of age, with an emphasis by Merck on marketing to pre-teen  
11 children and their parents.

12       50. With little evidence of efficacy, the FDA also recently approved, on an accelerated  
13 basis, Gardasil 9 for prevention of oropharyngeal and other head and neck cancers.

14       51. After the approval of the Gardasil 9 vaccine, the original Gardasil vaccine was phased  
15 out of the U.S. Market, and the original Gardasil vaccine is no longer available for sale in the United  
16 States.

17       52. According to data from the National Cancer Institute's ("NCI") Surveillance,  
18 Epidemiology and End Results Program ("SEER"), the incidence of deaths from cervical cancer prior  
19 to Gardasil's introduction in the United States had been steadily declining for years and, in 2006, was  
20 2.4 per 100,000 women or approximately 1 in every 42,000 women. The currently available rate is  
21 essentially unchanged, 2.2 per 100,000 women, based on data through 2017.

22       53. The median age of death from cervical cancer is 58, and death from anal cancer is 66,  
23 and teenagers (who are the target population of Gardasil) essentially have zero risk of dying from  
24 cervical or anal cancer.

25       54. Merck purchased fast-track review for Gardasil and Gardasil 9 under the Prescription  
26 Drug User Fee Act ("PDUFA"). Fast-track is a process designed to facilitate the development of  
27 drugs, and to expedite their review, in order to treat serious conditions and fill an unmet medical need.

28       55. Anxious to get Gardasil onto the market as soon as possible following the Vioxx

1 debacle, Merck sought fast-track approval even though there already existed a highly effective and  
2 side-effect free intervention, Pap smears, with no evidence that Gardasil was potentially superior to  
3 Pap smears in preventing cervical cancer.

4       56. In fact, the clinical trials Merck undertook did not even examine Gardasil’s potential to  
5 prevent cancer, rather, the trials only analyzed whether Gardasil could prevent potential precursor  
6 conditions, i.e., HPV infections and cervical interepithelial neoplasia (“CIN”) lesions graded from  
7 CIN1 (least serious) to CIN3 (most serious), the vast majority of which resolve on their own without  
8 intervention. CIN2 and CIN3 were the primary surrogate endpoints studied. Likewise, the clinical  
9 trials from Gardasil did not examine Gardasil’s potential to prevent anal cancer, rather, the trials  
10 similarly only look at anal intraepithelial neoplasia (“AIN”) lesions graded 1 through 3, and the  
11 Gardasil 9 studies did not even include any studies concerning the efficacy of Gardasil in preventing  
12 anal lesions.

13       57. According to the FDA, whether a condition is “serious” depends on such factors as  
14 “survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress  
15 from a less severe condition to a more serious one.”

16       58. As previously discussed, over 90 percent of HPV infections and the majority of cervical  
17 dysplasia resolve without intervention.

18       59. However, Merck presented misleading data to the FDA suggesting that CIN2 and CIN3  
19 inexorably result in cancer.

20       60. Federal law allows fast-track approval when there is no existing intervention to treat the  
21 targeted disease or where the proposed treatment is potentially superior to an existing treatment.

22       61. Merck knows (and knew) that Gardasil and Gardasil 9 are far less effective than Pap  
23 tests in preventing cervical cancer.

24       62. In order to obtain FDA approval, Merck designed and conducted a series of fraudulent  
25 Gardasil studies and then influenced the votes of the FDA’s Vaccines and Related Biological Products  
26 Advisory Committee (“VRBPAC”) and the CDC’s Advisory Committee on Immunization Practices  
27 (“ACIP”) to win both an FDA license and a CDC/ACIP approval and recommendation that all 11 and  
28 12 year old girls should be vaccinated with Gardasil.

1       63. That ACIP “recommendation” was, effectively, a mandate to doctors to sell Merck’s  
2 very expensive vaccine, thereby compelling parents of American children as young as nine years old  
3 to buy this expensive product. With ACIP’s recommendation, Merck was emboldened to build  
4 demand through direct-to-consumer advertising and door-to-door marketing to doctors, and, with the  
5 ACIP’s blessing of the vaccine, circumvented the need to create a traditional market for the product.

6       64. Julie Gerberding, then the Director of CDC, obligingly ushered the Gardasil vaccine  
7 through CDC’s regulatory process manifestly ignoring clear evidence that Gardasil’s efficacy was  
8 unproven and that the vaccine was potentially dangerous.

9       65. Merck, shortly thereafter, rewarded Gerberding by naming her President of Merck  
10 Vaccines in 2010.

11       66. In addition to the revolving regulatory/industry door (wherein the Director of CDC who  
12 approved the vaccine is subsequently employed by the manufacturer as a high-level executive to  
13 oversee the commercial success of the vaccine she previously approved), it is also worth noting some  
14 of the other conflicts of interest that exist within governmental agencies in relation to the facts  
15 surrounding Gardasil. Scientists from the National Institute of Health (“NIH”), which is a division of  
16 the United States Department of Health and Human Services (“HHS”), discovered a method of  
17 producing “virus-like-particles” (“VLPs”) that made creation of the Gardasil vaccine possible. The  
18 NIH scientists’ method of producing VLPs was patented by the Office of Technology Transfer  
19 (“OTT”), which is part of the NIH, and the licensing rights were sold to Merck (for manufacture of  
20 Gardasil). Not only does the NIH (and, in effect, the HHS) receive royalties from sales of Gardasil,  
21 but the scientists whose names appear on the vaccine patents can receive up to \$150,000 per year (in  
22 perpetuity). Accordingly, the Gardasil patents have earned HHS, NIH and the scientists who invented  
23 the technology millions of dollars in revenue.

24       67. Moreover, members of ACIP have been allowed to vote on vaccine recommendations  
25 even if they have financial ties to drug companies developing similar vaccines. According to a 2000  
26 U.S. House of Representatives investigation report, the majority of the CDC’s eight ACIP committee  
27 members had conflicts of interest. The Chairman of ACIP served on Merck’s Immunization Advisory  
28 Board and a number of the other ACIP members had received grants, salaries, or other forms of

1 remuneration from Merck.

2

3           **C. Merck Engaged in Disease Mongering and False Advertising to Enhance  
Gardasil Sales**

4           68. Both prior to and after the approval of Gardasil, Merck engaged in unscrupulous  
5 marketing tactics designed to overemphasize both the risks associated with HPV and the purported  
6 efficacy of Gardasil to scare the public into agreeing to mass vaccinations of the Gardasil vaccine.

7           69. Prior to Merck's aggressive marketing campaign, there was no HPV public health  
8 emergency in high-resource countries, such as the United States.

9           70. Most women had never heard of HPV. The NCI's 2005 Health Information National  
10 Trends Survey ("HINTS") found that, among U.S. women 18 to 75 years old, only 40 percent had  
11 heard of HPV. Among those who had heard of HPV, less than half knew of an association between  
12 HPV and cervical cancer. Furthermore, only four percent knew that the vast majority of HPV  
13 infections resolve without treatment.

14           71. The stage was set for Merck to "educate" the public about HPV, cervical cancer, and  
15 Gardasil, all to Merck's advantage.

16           72. Merck preceded its rollout of Gardasil with years of expensive disease awareness  
17 marketing. Merck ran "Tell Someone" commercials, designed to strike fear in people about HPV and  
18 cervical cancer – even ominously warning that you could have HPV and not know it. The  
19 commercials could not mention Gardasil, which had not yet been approved by FDA, but did include  
20 Merck's logo and name. Critics of Merck's pre-approval advertising and promotion called it  
21 "deceptive and dishonest." While Merck claims the promotion was part of public health education,  
22 critics complained that this "education" was designed to sell Gardasil and build the market for the  
23 vaccine. *See* Angela Zimm and Justin Blum, *Merck Promotes Cervical Cancer Shot by Publicizing  
Viral Cause*, BLOOMBERG NEWS, May 26, 2006.

25           73. A year before obtaining licensing for its vaccine, Merck engaged in a major offensive in  
26 "disease branding" to create a market for its vaccine out of thin air. *See* Beth Herskovits, *Brand of the  
Year*, PHARMEXEC.COM, February 1, 2007, at <http://www.pharmexec.com/brand-year-0>.

28           74. Merck also engaged in a relentless propaganda campaign aimed at frightening and

1 guiltig parents who failed to inoculate their children with Gardasil.

2       75. In addition to paid advertising, Merck worked with third parties to “seed” an obliging  
3 media with terrifying stories about cervical cancer in preparation for Merck’s Gardasil launch.

4       76. Prior to the FDA’s 2006 approval of Gardasil, the mainstream media – under direction  
5 of Merck and its agents – dutifully reported alarming cervical cancer stories, accompanied by the  
6 promotion of an auspicious vaccine.

7       77. Merck intended its campaign to create fear and panic and a public consensus that “good  
8 mothers vaccinate” their children with Gardasil. According to Merck propagandists, the only choice  
9 was to “get the vaccine immediately” or “risk cervical or anal cancer.”

10       78. Merck aggressively and fraudulently concealed the risks of the vaccine in broadcast  
11 materials and in propaganda that it disseminated in the United States.

12       79. Merck sold and falsely promoted Gardasil knowing that, if consumers were fully  
13 informed about Gardasil’s risks and dubious benefits, almost no one would have chosen to vaccinate.

14       80. Merck negligently and fraudulently deprived parents and children of their right to  
15 informed consent.

16       81. One of Merck’s television campaigns, conducted in 2016, shamelessly used child actors  
17 and actresses, implicitly dying of cancer, looking straight into the camera and asking their parents  
18 whether or not they knew that the HPV vaccine could have protected them against the HPV virus that  
19 caused them to develop their cancers. Each actor asked the following question: “Did you know?  
20 Mom? Dad?” See “Mom, Dad, did you know?” commercial: <https://www.ispot.tv/ad/Ap1V/know-hpv-hpv-vaccination>. Merck spent \$41 million over two months on the campaign. The ads said  
21 nothing about potential side effects. Merck also distributed pamphlets via U.S. mail to doctors ahead  
22 of the ad’s release to encourage them to share it with their patients:  
23

24

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82. Merck's fraudulent message was that cervical cancer and anal cancer were a real-life killer of young men and women, notwithstanding the fact that the average age for development of cervical cancer is 50 years old, average age of development of anal cancer is 60 years old and that the cancer is virtually nonexistent in men and women under 20.

83. Other television marketing campaigns Merck launched (including advertising that Plaintiff saw and relied upon in advance of consenting to her Gardasil injections) falsely proclaimed that Gardasil was a "cervical cancer vaccine" and that any young girl vaccinated with Gardasil would become "one less" woman with cervical cancer. The "One Less" marketing campaign portrayed Gardasil as if there were no question as to the vaccine's efficacy in preventing cervical cancer, and it disclosed none of Gardasil's side effects.

84. Merck marketed Gardasil with the most aggressive campaign ever mounted to promote a vaccine, spending more on Gardasil advertising than any previous vaccine advertising campaign.

21 **D. Merck Used Scare Tactics and Provided Financial Incentives to Legislatures to  
22 Attempt to make the Gardasil Vaccine Mandatory for All School Children**

23 85. An ACIP recommendation of a vaccine, adopted by individual states, opens the door to  
24 mandates affecting as many as four million children annually.

25 86. With Gardasil costing \$360 for the original three-dose series (exclusive of the necessary  
26 doctor's visits) and Gardasil 9 now priced at \$450 for two doses (again, not including the cost of  
27 doctor's visits), Merck stood to earn billions of dollars per year, in the US alone, with little marketing  
28 costs.

1       87. Prior to Gardasil’s approval in 2006, Merck was already targeting political figures to aid  
2 in the passage of mandatory vaccination laws.

3       88. As early as 2004, a group called Women in Government (“WIG”) started receiving  
4 funding from Merck and other drug manufacturers who had a financial interest in the vaccine.

5       89. With the help of WIG, Merck aggressively lobbied legislators to mandate Gardasil to all  
6 sixth-grade girls. *See Michelle Mello et al., Pharmaceutical Companies’ Role in State Vaccination*  
7 *Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AMERICAN J PUBLIC HEALTH  
8 893 (May 2012).

9       90. In 2006, Democratic Assembly leader Sally Lieber of California introduced a bill that  
10 would require all girls entering sixth grade to receive the Gardasil vaccination. Lieber later dropped  
11 the bill after it was revealed there was a possible financial conflict of interest.

12       91. Prior to the introduction of the bill, Lieber met with WIG representatives. In an  
13 interview, the President of WIG, Susan Crosby, confirmed that WIG funders have direct access to  
14 state legislators, in part through the organization’s Legislative Business Roundtable, of which WIG  
15 funders are a part. *See Judith Siers-Poisson, The Gardasil Sell Job*, in CENSORED 2009: THE TOP 25  
16 CENSORED STORIES OF 2007-08, 246 (Peter Philips ed. 2011).

17       92. Dr. Diane Harper, a medical doctor and scientist who was hired as a principal  
18 investigator on clinical trials for Gardasil gave an interview for an article on the HPV vaccines and  
19 WIG in 2007. Harper, who had been a major presenter at a WIG meeting in 2005, stated that “the  
20 Merck representative to WIG was strongly supporting the concept of mandates later in the WIG  
21 meetings and providing verbiage on which the legislators could base their proposals.”

22       93. WIG was one of dozens of “pay to play” lobby groups that Merck mobilized to push  
23 HPV vaccine mandates.

24       94. Another group, the National Association of County and City Health Officials  
25 (NACCHO), was also pushing HPV vaccine mandates in all 50 states.

26       95. To that end, Merck made large contributions to political campaigns and legislative  
27 organizations. By February 2007, 24 states and the District of Columbia had introduced mandate  
28 legislation.

1       96. Several states passed laws allowing preteen children as young as age 12 to “consent” to  
2 vaccination with an HPV vaccine without parental consent or knowledge.

3       97. One New York state county offered children free headphones and speakers to encourage  
4 them to consent to the Gardasil vaccine. *See* Mary Holland *et al.*, THE HPV VACCINE ON TRIAL:  
5 SEEKING JUSTICE FOR A GENERATION BETRAYED 131 (2018).

6       98. Merck funneled almost \$92 million to Maryland’s Department of Health between 2012  
7 and 2018 to promote Gardasil in Maryland schools, in a fraudulent campaign that paid school officials  
8 to deliberately deceive children and parents into believing Gardasil was mandatory for school  
9 attendance. Josh Mazer, *Maryland should be upfront about HPV vaccinations for children*, CAPITAL  
10 GAZETTE, August 14, 2018, at <https://www.capitalgazette.com/opinion/columns/ac-ce-column-mazer-20180814-story.html>.

12                   **E. Merck Pushed Gardasil Using Trusted Doctors and Third-Party Front Groups**

13       99. In order to mobilize “third-party credibility” to push Gardasil, Merck gave massive  
14 donations to dozens of nonprofit groups to “educate” the public via “education grants.” For example,  
15 a disclaimer on American College of Obstetricians and Gynecologists’ Immunization for Women  
16 website stated that “[t]his website is supported by an independent educational grant from Merck and  
17 Sanofi Pasteur US.”

18       100. Merck offered influential doctors (also known as “key opinion leaders”) \$4,500 for  
19 every Gardasil lecture they gave.

20       101. Among the allegedly independent organizations Merck recruited to push Gardasil were  
21 the Immunization Coalition, the Allegheny County Board of Health, the Eye and Ear Foundation, the  
22 Jewish Healthcare Foundation, the American Dental Association, the American College of  
23 Obstetricians and Gynecologists, and the American Cancer Society.

24                   **F. Merck Has Systematically Misrepresented the Efficacy of Gardasil By  
25 Advertising that Gardasil Prevents Cervical Cancer When There Are No  
Clinical Studies to Support This False Claim**

26       102. Merck faced a daunting problem in convincing regulators, doctors, and the public to  
27 accept the Gardasil vaccine.

28       103. Merck recommends the vaccine for children aged 11 to 12 years old, to provide

1 protection against a disease that, in the United States, is not generally diagnosed until a median age of  
2 50. Moreover, in those rare instances of death, the median age is 58.

3 104. There are no studies proving that Gardasil prevents cancer.

4 105. Because it can take decades for a persistent HPV infection to proceed to development of  
5 cervical or anal cancer, and because cervical and anal cancers are so rare, a true efficacy study would  
6 require decades and likely hundreds of thousand – if not millions – of trial participants to demonstrate  
7 that eliminating certain HPV infections would actually prevent the development of cervical and anal  
8 cancer.

9 106. Merck did not want to invest the time or money necessary to perform testing that would  
10 prove that its vaccine actually worked to prevent cervical and anal cancer.

11 107. Instead, Merck persuaded regulators to allow it to use “surrogate endpoints” to support  
12 its theory that the HPV vaccines would be effective in preventing cervical and anal cancer.

13 108. The clinical trials therefore did not test whether HPV vaccines prevent cervical, anal, or  
14 other cancers. Instead, Merck tested the vaccines against development of certain cervical lesions,  
15 which some researchers suspect are precursors to cancer, although the majority of these lesions – even  
16 the most serious – regress on their own. *See, e.g., Jin Yingji et al., Use of Autoantibodies Against*  
17 *Tumor-Associated Antigens as Serum Biomarkers for Primary Screening of Cervical Cancer*, 8  
18 ONCOTARGET 105425 (Dec. 1, 2017); Philip Castle et al., *Impact of Improved Classification on the*  
19 *Association of Human Papillomavirus With Cervical Precancer*, 171 AMERICAN JOURNAL OF  
20 EPIDEMIOLOGY 161 (Dec. 10, 2009); Karoliina Tainio et al., *Clinical Course of Untreated Cervical*  
21 *Intraepithelial Neoplasia Grade 2 Under Active Surveillance: Systematic Review and Meta-Analysis*,  
22 360 BRIT. MED. J. k499 (Jan. 16, 2018).

23 109. The Department of Health and Human Services (HHS), which oversees the FDA, and  
24 which also stood to make millions of dollars on the vaccine from patent royalties, allowed the use of  
25 Merck’s proposed surrogate endpoints.

26 110. The surrogate endpoints chosen by Merck to test the efficacy of its HPV vaccine were  
27 cervical and anal intraepithelial neoplasia (CIN) grades 2 and 3 and adenocarcinoma in situ.

28 111. Merck used these surrogate endpoints even though it knew that these precursor lesions

1 are common in young women under 25 and rarely progress to cancer.

2       112. At the time FDA approved the vaccine, Merck's research showed only that Gardasil  
3 prevented certain lesions (the vast majority of which would have resolved on their own without  
4 intervention) and genital warts – not cancer itself, and only for a few years at that.

5       113. The use of these surrogate endpoints allowed Merck to shorten the clinical trials to a  
6 few years and gain regulatory approvals of the vaccines without any evidence the vaccines would  
7 prevent cancer in the long run.

8       114. Merck's advertisements assert that the HPV vaccine prevents cervical cancer. For  
9 example, in a presentation to medical doctors, Merck proclaimed: "Every year that increases in  
10 coverage [of the vaccine] are delayed, another 4,400 women will go on to develop cervical cancer."  
11 The presentation goes on to tell doctors that women who do not get the vaccine will go on to develop  
12 cancer.

13       115. Merck's foundational theory that HPV alone causes cervical and anal cancer, while  
14 dogmatically asserted, is not proven.

15       116. Research indicates that cervical and anal cancer is a multi-factor disease with persistent  
16 HPV infections seeming to play a role, along with many other environmental and genetic factors,  
17 including smoking cigarettes or exposure to other toxic smoke sources, long-term use of oral  
18 contraceptives, nutritional deficiencies, multiple births (especially beginning at an early age), obesity,  
19 inflammation, and other factors. Not all cervical and anal cancer is associated with HPV types in the  
20 vaccines and not all cervical and anal cancer is associated with HPV at all.

21       117. Despite the lack of proof, Merck claimed that Gardasil could eliminate cervical and anal  
22 cancer and other HPV-associated cancers.

23       118. However, *Merck knows* that the Gardasil vaccines cannot eliminate all cervical and anal  
24 cancer or any other cancer that may be associated with HPV.

25       119. Even assuming the Gardasil vaccine is effective in preventing infection from the four to  
26 nine vaccine-targeted HPV types, the results may be short term, not guaranteed, and ignore the 200 or  
27 more other types of HPV not targeted by the vaccine, and some of which already have been associated  
28 with cancer.

1       120. Even assuming these vaccine-targets are the types solely responsible for 100 percent of  
2 cervical and anal cancer – which they are not – the vaccines have not been followed long enough to  
3 prove that Gardasil protects girls and boys from cancer that would strike them 40 years later.

4       121. Under Merck’s hypothetical theory, the reduction of pre-cancerous lesions should  
5 translate to fewer cases of cervical and anal cancer in 30 to 40 years.

6       122. Cervical and anal cancer takes decades to develop and there are no studies that prove  
7 the Gardasil vaccines prevent cancer.

8       123. In January 2020, a study from the UK raised doubts about the validity of the clinical  
9 trials in determining the vaccine’s potential to prevent cervical cancer. The analysis, carried out by  
10 researchers at Newcastle University and Queen Mary University of London, revealed many  
11 methodological problems in the design of the Phase 2 and 3 trials, leading to uncertainty regarding  
12 understanding the effectiveness of HPV vaccination. *See Claire Rees et al., Will HPV Vaccine*  
13 *Prevent Cancer?* J. OF THE ROYAL SOC. OF MED. 1-15 (2020).

14       124. As Dr. Tom Jefferson of the Centre for Evidence-Based Medicine pointed out: “The  
15 reason for choosing vaccination against HPV was to prevent cancer but there’s no clinical evidence to  
16 prove it will do that.”

17       125. Gardasil has never been proven to prevent cervical or any other kind of cancer.

18       126. Yet Merck has marketed the Gardasil vaccines as if there is no question regarding their  
19 efficacy at preventing cervical and anal cancer. In reality, they are at best protective against only four  
20 to nine of the over 200 strains of the human papillomavirus.

21           **G. The Gardasil Vaccines Contain Numerous Hazardous Ingredients, Including  
22 At Least One Ingredient Merck Failed to Disclose to Regulators and the Public**

23            *i. Gardasil Contains A Toxic Aluminum Adjuvant*

24       127. To stimulate an enhanced immune response that allegedly *might possibly* last for 50  
25 years, Merck added to the Gardasil vaccine a particularly toxic aluminum-containing adjuvant –  
26 Amorphous Aluminum Hydroxyphosphate Sulfate (“AAHS”).

27       128. Aluminum is a potent neurotoxin that can result in very serious harm.

28       129. The original Gardasil vaccine contains 225 micrograms of AAHS, and Gardasil 9

1 | contains 500 micrograms of AAHS.

2        130. Federal law requires that manufacturers cannot add adjuvants to vaccines that have not  
3 been proven safe. 21 C.F.R. § 610.15(a).

4        131. AAHS has never been proven safe. AAHS is a recent proprietary blend of aluminum  
5 and other unknown ingredients developed by Merck and used in Merck vaccines, including Gardasil.  
6 Prior vaccines have used a different aluminum formulation.

7        132. Peer-reviewed studies show that aluminum binds to non-vaccine proteins, including the  
8 host's own proteins, or to latent viruses, triggering autoimmune and other serious conditions. See  
9 Darja Kanduc, *Peptide Cross-reactivity: The Original Sin of Vaccines*, 4 FRONTIERS IN BIOSCIENCE  
10 1393 (June 2012).

11        133. Aluminum, including AAHS, has been linked to scores of systemic side effects  
12 including, but not limited to: impairing cognitive and motor function; inducing autoimmune  
13 interactions; increasing blood brain barrier permeability; inducing macrophagic myofascitis in muscle;  
14 blocking neuronal signaling; interrupting cell-to-cell communications; corrupting neuronal-glial  
15 interactions; interfering with synaptic transmissions; altering enzyme function; impairing protein  
16 function; fostering development of abnormal tau proteins; and altering DNA.

**ii. Merck Lied About a Secret DNA Adjuvant Contained in The Gardasil Vaccines**

19        134. Merck has repeatedly concealed or incorrectly identified Gardasil ingredients to the  
20 FDA and the public.

21        135. Merck lied both to the FDA and the public about including a secret and potentially  
22 hazardous ingredient, HPV LI-DNA fragments, in Gardasil. These DNA fragments could act as a  
23 Toll-Like Receptor 9 (“TLR9”) agonist – further adjuvanting the vaccine and making it more potent.  
24 Merck used this hidden adjuvant to prolong the immunological effects of the vaccine, but illegally  
25 omitted it from its list of substances and ingredients in the vaccine.

26       136. Dr. Sin Hang Lee has opined that, without adding the TLR9 agonist, Gardasil would not  
27 be immunogenic. The DNA fragments bound to the AAHS nanoparticles act as the TLR9 agonist in  
28 both Gardasil and Gardasil 9 vaccines, creating the strongest immune-boosting adjuvant in use in any

vaccine.

137. On multiple occasions, Merck falsely represented to the FDA and others, including regulators in other countries, that the Gardasil vaccine did not contain viral DNA, ignoring the DNA fragments.

138. This DNA adjuvant is not approved by the FDA and Merck does not list it among the ingredients as federal law requires. See 21 C.F.R. § 610.61(o) (requiring that adjuvants be listed on biologics' labeling). Even if not an adjuvant, the DNA fragments should have been listed because they represent a safety issue. 21 C.F.R. § 610.61(n).

139. It is unlawful for vaccine manufacturers to use an experimental and undisclosed adjuvant.

140. When independent scientists found DNA fragments in every Gardasil vial tested, from all over the world, Merck at first denied, and then finally admitted, the vaccine does indeed include HPV L1-DNA fragments.

141. Tellingly, Merck entered into a business arrangement with Idera Pharmaceuticals in 2006 to explore DNA adjuvants to further develop and commercialize Idera's toll-like receptors in Merck's vaccine program.

142. To this day, the Gardasil package inserts do not disclose that DNA fragments remain in the vaccine.

143. Dr. Lee also found HPV DNA fragments from the Gardasil vaccine in post-mortem spleen and blood samples taken from a young girl who died following administration of the vaccine. See Sin Hang Lee, *Detection of Human Papillomavirus L1 Gene DNA Fragments in Postmortem Blood and Spleen After Gardasil Vaccination—A Case Report*, 3 ADVANCES IN BIOSCIENCE AND BIOTECHNOLOGY 1214 (December 2018).

144. Those fragments appear to have played a role in the teenager's death.

145. The scientific literature suggests there are grave and little-understood risks attendant to injecting DNA into the human body.

### **iii. Gardasil Contains Borax**

146. Gardasil contains sodium borate (borax). Borax is a toxic chemical and may have long-

1 term toxic effects.

2       147. Merck has performed no studies to determine the impact of injecting borax into millions  
3 of young children or adults.

4       148. Sodium borate is known to have adverse effects on male reproductive systems in rats,  
5 mice, and dogs. Furthermore, borax causes increased fetal deaths, decreased fetal weight, and  
6 increased fetal malformations in rats, mice, and rabbits.

7       149. The European Chemical Agency requires a “DANGER!” warning on borax and states  
8 that borax “may damage fertility or the unborn child.”

9       150. The Material Safety Data Sheet (“MSDS”) for sodium borate states that sodium borate  
10 “[m]ay cause adverse reproductive effects” in humans.

11       151. The FDA has banned borax as a food additive in the United States, and yet allows  
12 Merck to use it in the Gardasil vaccine without any proof of safety.

13                          **iv.     Gardasil Contains Polysorbate 80**

14       152. Gardasil contains Polysorbate 80.

15       153. Polysorbate 80 crosses the blood-brain barrier.

16       154. Polysorbate 80 is used in drugs to open up the blood brain barrier in order to allow the  
17 active ingredients in a drug to reach the brain and to elicit the intended response. It acts as an  
18 emulsifier for molecules like AAHS and aluminum enabling those molecules to pass through resistive  
19 cell membranes.

20       155. Polysorbate 80 is associated with many health injuries, including, anaphylaxis,  
21 infertility and cardiac arrest.

22       156. Polysorbate 80 was implicated as a cause, possibly with other components, of  
23 anaphylaxis in Gardasil recipients in a study in Australia. *See Julia Brotherton et al., Anaphylaxis*  
24 *Following Quadrivalent Human Papillomavirus Vaccination*, 179 CANADIAN MEDICAL ASSOC. J. 525  
25 (September 9, 2008). Merck never tested Polysorbate 80 for safety in vaccines.

26                          **v.     Gardasil Contains Genetically Modified Yeast**

27       157. Gardasil contains genetically modified yeast.

28       158. Studies have linked yeast with autoimmune conditions. *See, e.g.*, Maurizo Rinaldi et

1 al., *Anti-Saccharomyces Cerevisiae Autoantibodies in Autoimmune Diseases: from Bread Baking to*  
2 *Autoimmunity*, 45 CLINICAL REVIEWS IN ALLERGY AND IMMUNOLOGY 152 (October 2013).

3 159. Study participants with yeast allergies were excluded from Gardasil clinical trials.

4 160. Merck has performed no studies to determine the safety of injecting yeast into millions  
5 of children and young adults.

6 **H. As it Did in Vioxx, In Designing and Conducting Its Clinical Trials for**  
7 **Gardasil, Merck Concealed Risks to Falsely Enhance the Safety Profile of**  
**Gardasil**

8 161. Merck engaged in wholesale fraud during its safety and efficacy clinical studies.

9 162. In order to obtain its Gardasil license, Merck designed its studies purposefully to  
10 conceal adverse events and exaggerate efficacy.

11 163. Merck sold Gardasil to the public falsely claiming that pre-licensing safety tests proved  
12 it to be effective and safe.

13 164. In fact, Merck's own pre-licensing studies showed Gardasil to be of doubtful efficacy  
14 and dangerous.

15 165. The dishonesty in the clinical tests has led many physicians to recommend the  
16 vaccination, under false assumptions.

17 166. The clinical trials clearly demonstrated that the risks of both Gardasil and Gardasil 9  
18 vastly outweigh any proven or theoretical benefits.

19 167. Merck deliberately designed the Gardasil protocols to conceal evidence of chronic  
20 conditions such as autoimmune diseases, menstrual cycle problems, and death associated with the  
21 vaccine during the clinical studies.

22 168. Merck employed deceptive means to cover up injuries that study group participants  
23 suffered.

24 169. In early 2018, Lars Jørgensen, M.D., Ph.D. and Professor Peter Gøtzsche, M.D. (then  
25 with the Nordic Cochrane Centre), and Professor Tom Jefferson, M.D. of the Centre for Evidence-  
26 Based Medicine published a study indexing all known industry and non-industry HPV vaccine clinical  
27 trials and were disturbed to find that regulators such as the FDA and EMA (European Medicines  
28 Agency) assessed as little as half of all available clinical trial results when approving the HPV

1 vaccines. Lars Jørgensen et al., *Index of the Human Papillomavirus (HPV) Vaccine Industry Clinical*  
2 *Study Programmers and Non-Industry Funded Studies: a Necessary Basis to Address Reporting Bias*  
3 *in a Systematic Review, 7 SYSTEMATIC REVIEWS* (January 18, 2018).

4 170. Per the indexing study discussed above, Merck appears to have kept a number of its  
5 clinical trial results secret. Moreover, it appears that Merck reported only those findings that support  
6 its own agenda.

7 171. Three separate reviews of the Gardasil vaccine by the Cochrane Collaboration found  
8 that the trial data were “largely inadequate.”

9 172. According to Dr. Tom Jefferson, “HPV [vaccine] harms have not been properly  
10 studied.”

11 173. In 2019, numerous medical professionals published an article in the British Medical  
12 Journal outlining the flaws and incomplete nature of the publications discussing Merck’s Gardasil  
13 clinical trials. The authors issued a “call to action” for independent researchers to reanalyze or  
14 “restore the reporting of multiple trials in Merck’s clinical development program for quadrivalent  
15 human papillomavirus (HPV) vaccine (Gardasil) vaccine.” Peter Doshi et al., *Call to Action: RIAT*  
16 *Restoration of Previously Unpublished Methodology in Gardasil Vaccine Trials*, 346 BRIT. MED. J.  
17 2865 (2019). The authors explained that the highly influential publications of these studies, which  
18 formed the basis of Gardasil’s FDA approval, “incompletely reported important methodological  
19 details and inaccurately describe the formulation that the control arm received, necessitating  
20 correction of the record.” *Id.* The authors explained that, while the publications claimed the clinical  
21 trials of Gardasil were “placebo-controlled,” “participants in the control arm of these trials did not  
22 receive an inert substance, such as saline injection. Instead, they received an injection containing  
23 [AAHS], a proprietary adjuvant system that is used in Gardasil to boost immune response.” *Id.*

24 174. The researchers further opined that “the choice of AAHS-containing controls  
25 complicates the interpretation of efficacy and safety results in trials ... We consider the omission in  
26 journal articles, of any rationale for the selection of AAHS-containing control, to be a form of  
27 incomplete reporting (of important methodological details) and believe the rationale must be reported.  
28 We also consider that use of the term ‘placebo’ to describe an active comparator like AAHS

1 | inaccurately describes the formulation that the control arm received, and constitutes an important error  
2 | that requires correction.” *Id.*

3        175. The authors pointed out that Merck's conduct "raises ethical questions about trial  
4 conduct as well" and that they and other scientists would need to review the Gardasil clinical trial raw  
5 data, in order to be able to analyze the safety and adverse event profile of Gardasil meaningfully and  
6 independently. *Id.*

### i. Small Clinical Trials

8        176. Although nine to 12-year-olds are the primary target population for HPV vaccines,  
9 Merck used only a small percentage of this age group in the clinical trials. Protocol 018 was the only  
10 protocol comparing children receiving a vaccine to those who did not. In that study, Merck looked at  
11 results of fewer than 1,000 children 12 and younger for a vaccine targeting billions of boys and girls  
12 in that age group over time. In Protocol 018, 364 girls and 332 boys (696 children) were in the  
13 vaccine cohort, while 199 girls and 173 boys (372 children) received a non-aluminum control.

14        177. The small size of this trial means that it was incapable of ascertaining all injuries that  
15 could occur as a result of the vaccine.

**ii. Merck Used a Highly Toxic “Placebo” to Mask Gardasil Injuries**

17        178. Instead of comparing health outcomes among volunteers in the Gardasil study group to  
18 health outcomes among volunteers receiving an inert placebo, Merck purposefully used a highly toxic  
19 placebo as a control in order to conceal Gardasil's risks in all trials using comparators with the  
20 exception of Protocol 018, where only 372 children received a non-saline placebo containing  
21 everything in the vaccine except the adjuvant and antigen.

179. Comparing a new product against an inactive placebo provides an accurate picture of  
the product's effects, both good and bad. The World Health Organization ("WHO") recognizes that  
using a toxic comparator as a control (as Merck did here) creates a "methodological disadvantage."  
WHO states that "it may be difficult or impossible to assess the safety" of a vaccine when there is no  
true placebo.

27        180. Merck deliberately used toxic “placebos” in the control group, in order to mask harms  
28 caused by Gardasil to the study group.

181. Instead of testing Gardasil against a control with a true inert placebo, Merck tested its vaccine in almost all clinical trials against its highly neurotoxic aluminum adjuvant, AAHS.

182. Merck gave neurotoxic aluminum injections to approximately 10,000 girls and young women participating in Gardasil trials, to conceal the dangers of Gardasil vaccines.

183. Merck never safety tested AAHS before injecting it into thousands of girls and young women in the control groups and the girls and young women were not told they could receive an aluminum “placebo.” Merck told the girls that they would receive either the vaccine or a safe inert placebo.

184. Merck violated rules and procedures governing clinical trials when it lied to the clinical study volunteers, telling them that the placebo was an inert saline solution – when in reality the placebo contained the highly neurotoxic aluminum adjuvant AAHS.

185. AAHS provoked terrible injuries and deaths in a number of the study participants when Merck illegally dosed the control group volunteers with AAHS.

186. Since the injuries in the Gardasil group were replicated in the AAHS control group, this scheme allowed Merck to falsely conclude that Gardasil's safety profile was comparable to the "placebo."

187. The scheme worked and enabled Merck to secure FDA licensing.

188. Merck lied to the FDA when it told public health officials that it had used a saline placebo in Protocol 018.

189. There was no legitimate public health rationale for Merck's failure to use a true saline placebo control in the original Gardasil clinical trials. At that time, no other vaccine was yet licensed for the four HPV strains Gardasil was intended to prevent.

190. A small handful of girls in a subsequent Gardasil 9 trial group, may have received the saline placebo, but only after they had already received three doses of Gardasil for the Gardasil 9 trial.

**iii. Merck Used Exclusionary Criteria to Further Conceal Gardasil Risks**

191. Merck also manipulated the Gardasil studies by excluding nearly half of the original recruits to avoid revealing the effects of the vaccine on vulnerable populations.

1       192. After recruiting thousands of volunteers to its study, Merck excluded all women who  
2 had admitted to vulnerabilities that might be aggravated by the vaccine such as abnormal Pap tests or  
3 a history of immunological or nervous system disorders.

4       193. Women could also be excluded for “[a]ny condition which in the opinion of the  
5 investigator might interfere with the evaluation of the study objectives.”

6       194. Merck’s protocol had exclusion criteria for subjects with allergies to vaccine ingredients  
7 including aluminum (AAHS), yeast, and the select enzymes. For most of these ingredients, there are  
8 limited resources for the public to test for such allergies in advance of being vaccinated.

9       195. Merck excluded anyone with serious medical conditions from the Gardasil clinical  
10 trials, even though CDC recommends the Gardasil vaccine for everyone, regardless of whether or not  
11 they suffer from a serious medical condition.

12       196. Merck sought to exclude from the study all subjects who might be part of any subgroup  
13 that would suffer injuries or adverse reactions to any of Gardasil’s ingredients.

14       197. The study exclusion criteria are not listed as warnings on the package inserts and the  
15 package insert for Gardasil only mentions an allergy to yeast or to a previous dose of Gardasil as a  
16 contraindication, rather than an allergy to any other component. Nonetheless, for most of the  
17 ingredients, it is almost impossible to determine if such an allergy exists prior to being vaccinated and  
18 Merck does not recommend allergy testing before administering the vaccine.

19       198. Instead of testing the vaccine on a population representative of the cross-section of  
20 humans who would receive the approved vaccine, Merck selected robust, super-healthy trial  
21 participants, who did not reflect the general population, in order to mask injurious effects on all the  
22 vulnerable subgroups that now receive the vaccine. Therefore, the population tested in the clinical  
23 trials was a much less vulnerable population than the population now receiving Gardasil.

24                          **iv. Merck Deceived Regulators and The Public by Classifying Many  
25                          Serious Adverse Events, Which Afflicted Nearly Half of All Study  
                        Participants, As Coincidences**

26       199. Because Merck did not use a true placebo, determining which injuries were attributable  
27 to the vaccine and which were attributable to unfortunate coincidence was entirely within the  
28 discretion of Merck’s paid researchers.

200. In order to cover up and conceal injuries from its experimental vaccine, Merck, during the Gardasil trials, employed a metric, “new medical conditions,” that allowed the company to dismiss and fraudulently conceal infections, reproductive disorders, neurological symptoms, and autoimmune conditions, which affected a troubling 50 percent of all clinical trial participants.

201. Merck's researchers systematically dismissed reports of serious adverse events from 49 percent of trial participants in order to mask the dangers of the vaccine.

7        202. Instead of reporting these injuries as “adverse events,” Merck dismissed practically all  
8 of these illnesses and injuries as unrelated to the vaccine by classifying them under its trashcan metric  
9 “new medical conditions” – a scheme Merck could get away with only because it used a “spiked”  
10 (poisonous) placebo, that was yielding injuries at comparable rates.

11        203. Merck's use of a toxic placebo allowed the company to conceal from the public an  
12 epidemic of autoimmune diseases and other injuries and deaths associated with its multi-billion-dollar  
13 HPV vaccine.

14        204. Because Merck conducted its studies without a true placebo, Merck investigators had  
15 wide discretion to decide what constituted an adverse event and used that power to dismiss a wave of  
16 grave vaccine injuries, injuries that sickened half of the trial volunteers, as coincidental.

17        205. Almost half (49 percent) of all trial participants, regardless of whether they received the  
18 vaccine or Merck's toxic placebo, reported adverse events, including serious illnesses such as blood,  
19 lymphatic, cardiac, gastrointestinal, immune, musculoskeletal, reproductive, neurological and  
20 psychological conditions, chronic illnesses such as thyroiditis, arthritis and multiple sclerosis, and  
21 conditions requiring surgeries. *See, e.g., Nancy B. Miller, Clinical Review of Biologics License*  
22 *Application for Human Papillomavirus 6, 11, 16, 18 L1 Virus Like Particle Vaccine (S. cerevisiae)*  
23 *(STN 125126 GARDASIL), manufactured by Merck, Inc. at 393-94 (Table 302) (June 8, 2006).*

v. **Merck Manipulated the Study Protocols to Block Participants and Researchers from Reporting Injuries and Designed the Studies to Mask Any Long-Term Adverse Events**

206. Merck adopted multiple strategies to discourage test subjects from reporting injuries.

27        207. Merck provided Vaccination Report Cards to a limited number of trial participants. For  
28 example, in Protocol 015, only approximately 10 percent of participants – all in the United States,

1 despite trial sites worldwide – received Vaccination Report Cards to memorialize reactions in the first  
2 few days following injections.

3       208. Furthermore, the report cards only included *categories* of “Approved Injuries” mainly  
4 jab site reactions (burning, itching, redness, bruising) – leaving no room to report more serious  
5 unexplained injuries such as autoimmune diseases. In fact, they were designed for the purposes of  
6 reporting non-serious reactions only.

7       209. Furthermore, Merck instructed those participants to record information for only 14 days  
8 following the injection.

9       210. In this way, Merck foreclosed reporting injuries with longer incubation periods or  
10 delayed diagnostic horizons.

11       211. Abbreviated reporting periods were part of Merck’s deliberate scheme to conceal  
12 chronic conditions such as autoimmune or menstrual cycle problems, and premature ovarian failure,  
13 all of which have been widely associated with the vaccine, but would be unlikely to show up in the  
14 first 14 days following injection.

15       212. Merck researchers did not systematically collect adverse event data, from the trials,  
16 which were spread out over hundreds of test sites all over the world.

17       213. To conceal the dangerous side effects of its vaccine, Merck purposely did not follow up  
18 with girls who experienced serious adverse events during the Gardasil clinical trials.

19       214. Merck failed to provide the trial subjects a standardized questionnaire checklist of  
20 symptoms, to document a comparison of pre- and post-inoculation symptoms.

21       215. To discourage its clinicians from reporting adverse events, Merck made the paperwork  
22 reporting requirements for supervising clinicians, onerous and time-consuming, and refused to pay  
23 investigators additional compensation for filling out the paperwork.

24       216. Thus, Merck disincentivized researchers from reviewing participants’ medical records  
25 even when the participant developed a “serious medical condition that meets the criteria for serious  
26 adverse experiences” as described in the protocol.

27       217. Merck granted extraordinary discretion to its researchers to determine what constituted  
28 a reportable adverse event, while incentivizing them to report nothing and to dismiss all injuries as

1 unrelated to the vaccine.

2 218. Merck used subpar, subjective data collection methods, relying on participants'  
3 recollections and the biased viewpoints of its trial investigators.

4 219. Merck downplayed the incidence of serious injuries and used statistical gimmickry to  
5 under-report entries.

6 220. During its Gardasil clinical trials, Merck failed to adequately capture and properly code  
7 adverse events and symptoms, including but not limited to adverse events and symptoms that were  
8 indicative of autoimmune or neurological injuries, including but not limited to POTS and CRPS, so as  
9 to prevent the medical community, regulators and patients from learning about these adverse events  
10 and to avoid the responsibility of having to issue appropriate warnings concerning these adverse  
11 events.

12 vi. **Merck Deceived Regulators and the Public About Its Pivotal**  
**Gardasil Clinical Trial (Protocol 018)**

14 221. Merck tested Gardasil and Gardasil 9 in some 50 clinical trials, each one called a  
15 "Protocol." However, results for many of these studies are not available to the public or even to the  
16 regulators licensing Gardasil. See Lars Jørgensen, *et al.*, *Index of the Human Papillomavirus (HPV)*  
17 *Vaccine Industry Clinical Study Programmers and Non-Industry Funded Studies: a Necessary Basis*  
18 *to Address Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEWS 8 (January 18, 2018).

19 222. Gardasil's most important clinical trial was Protocol 018. The FDA considered  
20 Protocol 018 the pivotal trial upon which Gardasil licensing approvals hinged, because FDA believed  
21 1) it was the only trial where Merck used a "true saline placebo," and 2) it was the only trial with a  
22 comparator group that included girls aged 11 to 12 – the target age for the Gardasil vaccine. See  
23 Transcript of FDA Center For Biologics Evaluation And Research VRBPAC Meeting, May 18, 2006,  
24 at 93 (Dr. Nancy Miller).

25 223. Merck lied to regulators, to the public and to subjects in its clinical trials by claiming  
26 that the Protocol 018 "placebo" group received an actual saline or inert placebo.

27 224. When the FDA approved Gardasil, it described the Protocol 018 control as a "true  
28 saline placebo."

1       225. The FDA declared that the Protocol 018 trial was “of particular interest” because Merck  
2 used a true saline placebo instead of the adjuvant as a control.

3       226. Merck told regulators that it gave a “saline placebo” to only one small group of  
4 approximately 600 nine to 15-year-old children.

5       227. In fact, Merck did not give even this modest control group a true saline placebo, but  
6 rather, the group members were given a shot containing “the carrier solution” – a witch’s brew of  
7 toxic substances including polysorbate 80, sodium borate (borax), genetically modified yeast, L-  
8 histidine, and possibly a fragmented DNA adjuvant.

9       228. The only components of Gardasil the control group did not receive were the HPV  
10 antigens and the aluminum adjuvant.

11       229. Despite the witches’ brew of toxic chemicals in the carrier solution, those children fared  
12 much better than any other study or control group participants, all of whom received the AAHS  
13 aluminum adjuvant.

14       230. Only 29 percent of the vaccinated children and 31 percent of control recipients in  
15 Protocol 018 reported new illnesses from Day 1 through Month 12, compared to an alarming 49.6  
16 percent of those vaccinated and 49 percent of AAHS controls in the “pooled group” (composed of  
17 some 10,000 young women and with the other participants combined) from Day 1 only through  
18 Month 7 (not 12). Because the pooled group also included Protocol 018, even those numbers may not  
19 be accurate with respect to those who received either a vaccine with a full dose of AAHS or those who  
20 received an AAHS control.

21       231. Few of the participants in the Protocol 018 control group got systemic autoimmune  
22 diseases, compared to 2.3 percent (1 in every 43) in the pooled group. In a follow-up clinical review  
23 in 2008, the FDA identified three girls in the carrier-solution group with autoimmune disease. Based  
24 on the number of girls in the placebo group as stated in the original 2006 clinical review, fewer than 1  
25 percent of girls in the carrier solution group reported autoimmune disease.

26       232. In order to further deceive the public and regulators, upon information and belief,  
27 Merck cut the dose of aluminum adjuvant in half when it administered the vaccine to the nine to  
28 fifteen-year-old children in its Protocol 018 study group.

1       233. As a result, this group showed significantly lower “new medical conditions” compared  
2 to other protocols.

3       234. Upon information and belief, Merck pretended that the vaccinated children in the  
4 Protocol 018 study group received the full dose adjuvant by obfuscating the change in formulation in  
5 the description.

6       235. Upon information and belief, Merck had cut the adjuvant in half, knowing that this  
7 would artificially and fraudulently lower the number of adverse events and create the illusion that the  
8 vaccine was safe.

9       236. Upon information and belief, Merck lied about this fact to the FDA.

10      237. The data from that study therefore do not support the safety of the Gardasil formulation  
11 since Merck was not testing Gardasil but a far less toxic formulation.

12      238. Upon information and belief, Merck was testing a product with only half the dose of  
13 Gardasil’s most toxic component.

14      239. Upon information and belief, this is blatant scientific fraud, which continues to this day  
15 because this is the study upon which current vaccine safety and long-term efficacy assurances are  
16 based.

17      240. As set forth above, upon information and belief, Merck’s deception served its purpose:  
18 Only 29 percent of the vaccinated children in Protocol 018 reported new illness, compared to an  
19 alarming 49.6 percent in the pooled group to receive the full dose adjuvant in the vaccine.

20           **I. Contrary to Merck’s Representations, Gardasil May Actually Cause and  
21 Increase the Risk of Cervical and Other Cancers**

22      241. Gardasil’s label states, “Gardasil has not been evaluated for potential to cause  
23 carcinogenicity or genotoxicity.” The Gardasil 9 label states: “GARDASIL9 has not been evaluated  
24 for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility.”

25      242. Peer-reviewed studies, including CDC’s own studies, have suggested that the  
26 suppression of the HPV strains targeted by the Gardasil vaccine may actually open the ecological  
27 niche for replacement by more virulent strains. *See Fangjian Guo et al., Comparison of HPV*  
28 *prevalence between HPV-vaccinated and non-vaccinated young adult women (20–26 years),* 11

1 HUMAN VACCINES & IMMUNOTHERAPEUTICS 2337 (October 2015); Sonja Fischer et al., *Shift in*  
2 *prevalence of HPV types in cervical cytology specimens in the era of HPV vaccinations*, 12  
3 ONCOLOGY LETTERS 601 (2016); J. Lyons-Weiler, *Biased Cochrane Report Ignores Flaws in HPV*  
4 *Vaccine Studies, and Studies of HPV Type Replacement* (May 18, 2018). In other words, Gardasil  
5 may increase the chances of getting cancer.

6 243. In short, the Gardasil vaccines, which Merck markets as anti-cancer products, may  
7 themselves cause cancer or mutagenetic changes that can lead to cancer.

8 244. Merck concealed from the public data from its clinical trials indicating that the vaccines  
9 enhance the risk of cervical cancers in many women.

10 245. Merck's study showed that women exposed to HPV before being vaccinated were 44.6  
11 percent more likely to develop cancerous lesions compared to unvaccinated women, even within a few  
12 years of receiving the vaccine.

13 246. In other words, Merck's studies suggest that its HPV vaccines may cause cancer in  
14 women who have previously been exposed to HPV, particularly if they also have a current infection.

15 247. In some studies, more than 30 percent of girls show evidence of exposure to HPV  
16 before age ten, from casual exposures, unwashed hands or in the birth canal. Flora Bacopoulou et al.,  
17 *Genital HPV in Children and Adolescents: Does Sexual Activity Make a Difference?*, 29 JOURNAL OF  
18 PEDIATRIC & ADOLESCENT GYNECOLOGY 228 (June 2016).

19 248. Even in light of the data demonstrating that Gardasil can increase the risk of cancer in  
20 girls who previously have been exposed to HPV, in order to increase profits, Merck's Gardasil labels  
21 and promotional material do not inform patients and medical doctors of this important risk factor.

22 249. Some clinical trial participants have developed cancer, including cervical cancer.

23 250. Numerous women have reported a sudden appearance of exceptionally aggressive  
24 cervical cancers following vaccination.

25 251. Cervical cancer rates are climbing rapidly in all the countries where Gardasil has a high  
26 uptake.

27 252. An Alabama study shows that the counties with the highest Gardasil uptakes also had  
28 the highest cervical cancer rates.

1       253. After the introduction of HPV Vaccine in Britain, cervical cancer rates among young  
2 women aged 25 to 29 has risen 54 percent.

3       254. In Australia, government data reveals there has been a sharp increase in cervical cancer  
4 rates in young women following the implementation of the Gardasil vaccine. The most recent data  
5 reveal that, 13 years after Gardasil was released and pushed upon teenagers and young adults, there  
6 has been a 16 percent increase in 25- to 29-year-olds, and a 30 percent increase in 30 to 34 year-old  
7 girls contracting cervical cancer – corroborating the clinical trial data that Gardasil may *increase* the  
8 risk of cervical cancer, particularly in patients who had previous HPV infections. Meanwhile, rates  
9 are decreasing for older women (who have not been vaccinated).

10      255. In addition to the belief that Gardasil may create and open an ecological niche for  
11 replacement by more virulent strains of HPV, resulting in the increase of cervical cancers as outlined  
12 above, in light of Merck's false advertising that Gardasil prevents cervical cancer, young women who  
13 have received Gardasil are foregoing regular screening and Pap tests in the mistaken belief that HPV  
14 vaccines have eliminated all their risks.

15      256. Cervical screening is proven to reduce the cases of cervical cancer, and girls who have  
16 taken the vaccine are less likely to undergo cervical screenings.

17      257. Data show that girls who received HPV vaccines before turning 21 are far less likely to  
18 get cervical cancer screening than those who receive the vaccines after turning 21.

19      258. The cervical screening is more cost effective than vaccination alone or vaccination with  
20 screening.

21      259. Therefore, Pap tests, which detect cervical tissue abnormalities, and HPV DNA testing  
22 are the most effective frontline public health response to cervical health.

23      **J. Merck has Concealed the Fact that Gardasil Induces and Increases the Risk of**  
24 **Autoimmune Diseases, and Other Injuries, Including But Not Limited to,**  
25 **Postural Orthostatic Tachycardia Syndrome, Chronic Fatigue Syndrome,**  
**Neuropathy, Fibromyalgia and Dysautonomia**

26      260. Gardasil induces and increases the risk of autoimmune disease.

27      261. Gardasil has been linked to a myriad of autoimmune disorders, including but not  
28 limited, to: Guillain–Barré syndrome (“GBS”), postural orthostatic tachycardia syndrome (“POTS”),

1 Orthostatic Intolerance (“OI”), chronic inflammatory demyelinating polyneuropathy (“CDIP”), small  
2 fiber neuropathy (“SNF”), systemic lupus erythematosus (“SLE”), immune thrombocytopenic purpura  
3 (“ITP”), multiple sclerosis (“MS”), acute disseminated encephalomyelitis (“ADEM”),  
4 antiphospholipid syndrome (“APS”), transverse myelitis, rheumatoid arthritis, interconnective tissue  
5 disorder, autoimmune pancreatitis (“AIP”) and autoimmune hepatitis.

6        262. Gardasil has also been linked to a myriad of diseases and symptoms that are associated  
7 with induced-autoimmune disease, including for example, fibromyalgia, dysautonomia, premature  
8 ovarian failure, chronic fatigue syndrome (“CFS”), chronic regional pain syndrome (“CRPS”),  
9 cognitive dysfunction, migraines, severe headaches, persistent gastrointestinal discomfort, widespread  
10 pain of a neuropathic character, encephalitis syndrome, autonomic dysfunction, joint pain, and brain  
11 fog.

12        263. In a 2015 textbook, VACCINES AND AUTOIMMUNITY, edited by Dr. Yehuda Shoenfeld,  
13 the father of autoimmunology research, and many of the world’s leading autoimmunity experts, the  
14 scientists concluded that Gardasil can cause autoimmune disorders because of the vaccine’s strong  
15 immune stimulating ingredients. *See* Lucija Tomljenovic & Christopher A. Shaw, *Adverse Reactions*  
16 *to Human Papillomavirus Vaccines*, VACCINES & AUTOIMMUNITY 163 (Yehuda Shoenfeld et al. eds.,  
17 2015).

18        264. Medical experts have opined that the mixture of adjuvants contained in vaccines, in  
19 particular in the Gardasil vaccines, is responsible for post-vaccination induced autoimmune diseases  
20 in select patients. The risks have become so prolific that medical experts have coined a new umbrella  
21 syndrome – Autoimmune/Inflammatory Syndrome Induced by Adjuvants (“ASIA”) to refer to the  
22 spectrum of immune-mediated diseases triggered by an adjuvant stimulus contained in vaccines, such  
23 as aluminum. *See, e.g.*, YEHUDA SHOENFELD ET AL, EDS., VACCINES & AUTOIMMUNITY 2 (2015)

24        265. Indeed, even in animal studies, it has been revealed that aluminum adjuvants can induce  
25 autoimmune disease in tested animals. By way of example, in a series of studies conducted by Lluís  
26 Luján, DVM, Ph.D., and his colleagues, it was revealed that sheep injected with aluminum-containing  
27 adjuvants commonly come down with severe autoimmune diseases and other adverse reactions.

28        266. Specific to the Gardasil vaccines, which contain adjuvants, including, amorphous

1 aluminum hydroxyphosphate sulfate (AAHS) and the previously undisclosed HPV L1 gene DNA  
2 fragments, a number of mechanisms of action have been outlined (as discussed *infra*) as to how  
3 Gardasil induces autoimmune disease in select patients.

4       267. Given the number of HPV strains that exist, a great part of the human population has  
5 HPV, however, HPV by itself is generally not immunogenic, and generally does not evoke immune  
6 responses. Indeed, HPV shares a high number of peptide sequences with human proteins, so that the  
7 human immune system generally does not react against HPV in order to not harm self-proteins.  
8 Immunotolerance thus generally blocks reactions against HPV in order to avoid autoimmune attacks  
9 against the human proteins.

10       268. To induce anti-HPV immune reactions, Merck added various adjuvants, including  
11 amorphous aluminum hydroxyphosphate sulfate (AAHS), to the Gardasil vaccine. Adjuvants, such as  
12 aluminum, are inflammatory substances that hyperactivate the immune system. Adjuvants are thus  
13 the “secret sauce” used by Merck to hyperactivate the immune system and make HPV immunogenic.

14       269. While adjuvants are added with the intent of destroying the HPV virus, they also can  
15 have the unintended result of rendering the immune system “blind” and unable to distinguish human  
16 proteins from HPV proteins – accordingly, human proteins that share peptide sequences with HPV are  
17 at risk of also being attacked by the vaccine.

18       270. While Gardasil causes immune hyperactivation and production of anti-HPV antibodies  
19 to fend off certain strains of the HPV virus, it can also result in the immune system losing its ability to  
20 differentiate human proteins from foreign proteins causing the immune system to attack the body’s  
21 own proteins and organs. Because of the massive peptide commonality between HPV and human  
22 proteins, the indiscriminate attack triggered by the Gardasil adjuvants will cause massive cross-  
23 reactions and dangerous attacks against human proteins, leading to a number of autoimmune diseases  
24 manifested throughout the different organs of the body. This process is sometimes referred to as  
25 “molecular mimicry.”

26       271. In addition to “molecular mimicry,” other mechanisms of action that explain how  
27 Gardasil can induce autoimmune disease are “epitope spreading,” whereby invading Gardasil  
28 antigens, including the toxic aluminum adjuvant, accelerate autoimmune process by location

1 activation of antigen presenting cells and “bystander activation,” wherein antigens and the aluminum  
2 adjuvants in the Gardasil vaccine activate pre-primed autoreactive T cells, which can initiate  
3 autoimmune disease (bystander activation of autoreactive immune T cells), or where virus-specific T  
4 cells initiate bystander activation resulting in the immune system killing uninfected and unintended  
5 neighboring cells.

6        272. Relevant to the injuries at issue in this case, when a person is lying down,  
7 approximately one-quarter of their blood volume resides in the chest area. When the person stands  
8 up, a significant amount of that blood shifts to the lower extremities. This causes impaired return of  
9 blood flow to the heart which also reduces blood pressure. In healthy individuals, the autonomic  
10 nervous system adjusts the heartrate to counteract this effect and the hemodynamic changes are  
11 negligible. However, in individuals (such as Plaintiff) who are now suffering from dysautonomia or  
12 autonomic ailments, such as Neurocardiogenic Syncope, POTS or OI, the body’s ability to adjust the  
13 heartrate and compensate for the blood flow is corrupted resulting in a host of wide ranging  
14 symptoms, including but not limited to, dizziness, lightheadedness, vertigo, woozy sensation, chronic  
15 headaches, vision issues due to the loss of blood flow to the brain, light and sound sensitivity, loss of  
16 consciousness, shortness of breath, chest pain, gastrointestinal issues, body pains, insomnia, and  
17 confusion and/or difficulty sleeping. In certain cases of POTS, patients will also be diagnosed with  
18 other medical conditions, including but not limited to, chronic fatigue syndrome and fibromyalgia.

19        273. Medical research has determined that certain dysautonomia diseases such as POTS and  
20 OI have an autoimmune etiology. Norepinephrine, a key neurotransmitter of the sympathetic (“fight  
21 or flight”) system, exerts its mechanism of action by binding to receptors located in the smooth  
22 muscle of the blood vessels and various organs, including the heart. These receptors include alpha-1,  
23 alpha-2, beta-1, beta-2, and beta-3 receptors and, as a group, are generally known as the adrenergic  
24 receptors. The adrenergic receptors, and other receptors, including but not limited to, the ganglionic  
25 and muscarinic acetylcholine receptors are believed to be affected in certain cases of POTS and OI.  
26 See e.g., Hongliang Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. AMERICAN  
27 HEART ASSOC. e000755 (2014); Artur Fedorowski et al., *Antiadrenergic Autoimmunity in Postural*  
28 *Tachycardia Syndrome*, 19 EUROPACE 1211 (2017); Mohammed Ruzieh et al., *The Role of*

1 *Autoantibodies in the Syndromes of Orthostatic Intolerance: A Systematic Review*, 51 SCANDINAVIAN  
2 CARDIOVASCULAR J. 243 (2017); Shu-ichi Ikeda et al., *Autoantibodies Against Autonomic Nerve*  
3 *Receptors in Adolescent Japanese Girls after Immunization with Human Papillomavirus Vaccine*, 2  
4 ANNALS OF ARTHRITIS AND CLINICAL RHEUMATOLOGY 1014 (2019); William T. Gunning, *Postural*  
5 *Orthostatic Tachycardia Syndrome is Associated With Elevated G-Protein Coupled Receptor*  
6 *Autoantibodies*, 8 J. AMERICAN HEART ASSOC. e013602 (2019).

7 274. A variety of published medical journal articles have discussed the association between  
8 Gardasil and a myriad of serious injuries and have reported on patients developing POTS, OI,  
9 fibromyalgia and other symptoms of autonomic impairment following Gardasil vaccination. See  
10 Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN  
11 J. OF NEUROLOGY e52 (2010); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following*  
12 *Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135 (2014); Tomomi Kinoshita  
13 et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following*  
14 *Immunization With Human Papillomavirus Vaccine*, 53 INTERNAL MEDICINE 2185 (2014); Louise S.  
15 Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse*  
16 *Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-  
17 Lavin et al., *HPV Vaccination Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL  
18 RHEUMATOLOGY 1981 (2015); Louise S. Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic*  
19 *Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma*  
20 *Virus Vaccine*, 1 INT. J. OF VACCINE & VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity,*  
21 *Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS  
22 (2017); Rebecca E. Chandler et al., *Current Safety Concerns With Human Papillomavirus Vaccine: A*  
23 *Cluster Analysis of Reports in VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al.,  
24 *Autonomic Dysfunction and HPV Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and  
25 Svetlana Blitshetyn, *Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and*  
26 *Related Conditions*, CLINICAL AUTONOMIC RESEARCH (2019).

27 275. In a 2017 review, Drs. Tom Jefferson and Lars Jørgensen criticized the European  
28 Medicines Agency (“EMA”) for turning a blind eye to the debilitating autoimmune injuries, including

1 CRPS and POTS that young women had suffered following vaccination with HPV vaccine. Tom  
2 Jefferson et al., *Human Papillomavirus Vaccines, Complex Regional Pain Syndrome, Postural*  
3 *Orthostatic Tachycardia Syndrome, and Autonomic Dysfunction – A Review of the Regulatory*  
4 *Evidence from the European Medicines Agency*, 3 INDIAN J. OF MED. ETHICS 30 (Jan. – March 2017).

5 276. In a separate article, the same authors describe their process for extracting data from not  
6 only peer-reviewed journal publications, but also unpublished data from pharmaceutical company  
7 clinical study reports and trial register entries from ClinicalTrials.gov, under the assumption that  
8 “more than half of all studies are never published, and the published studies’ intervention effects are  
9 often exaggerated in comparison to the unpublished studies. This introduces reporting bias that  
10 undermines the validity of systematic reviews. To address reporting bias in systematic reviews, it is  
11 necessary to use industry and regulatory trial registers and trial data—in particular, the drug  
12 manufacturers’ complete study programs.” They found that 88 percent of industry studies were solely  
13 industry funded and found serious deficiencies and variability in the availability of HPV vaccine study  
14 data. For example, only half of the completed studies listed on ClinicalTrials.gov posted their results.  
15 The clinical study reports the authors obtained confirmed that the amount of information and data are  
16 vastly greater than that in journal publications. When the authors compared the data the EMA used  
17 (which was provided by GlaxoSmithKline and Merck Sharp and Dohme) to conduct their review of  
18 the relationship between HPV vaccination and both POTS and CRPS, the authors found that only 48  
19 percent of the manufacturers’ data were reported. According to the authors, “we find this very  
20 disturbing.” Lars Jørgensen et al., *Index of the Human Papillomavirus (HPV) Vaccine Industry*  
21 *Clinical Study Programmes and Non-Industry Funded Studies: A Necessary Basis to Address*  
22 *Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEW 8 (2018).

23 277. Likewise, in a recently released February 2020 peer-reviewed study, researchers who  
24 analyzed the available clinical trial data for all HPV vaccines, which include the Gardasil vaccines and  
25 another HPV vaccine currently only available in Europe, concluded that “HPV vaccines increased  
26 serious nervous disorders.” Lars Jørgensen et al., *Benefits and Harms of the Human Papillomavirus*  
27 *(HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports*, 9  
28 SYSTEMATIC REVIEWS 43 (February 2020).

278. In addition, Jørgensen and his co-authors observed that, in reanalyzing the association between HPV vaccines and one specific autoimmune disease, POTS, the HPV vaccines were associated with a nearly two-fold increased risk of POTS. *Id.*

279. Jørgensen and his co-authors also noted many of the same shortcomings associated with the Gardasil clinical trials as have already been discussed in this Complaint, including for example, the fact that no true placebo was utilized by Merck as a comparator (i.e., the comparator/control used by Merck in the Gardasil clinical trials contained aluminum adjuvant). The researchers noted that “[t]he use of active comparators may have underestimated harms related to HPV vaccines,” and that “[t]he degree of harms might therefore be higher in clinical practice than in the trials.” *Id.*

280. Jørgensen and his co-authors also noted that the clinical trials revealed that Gardasil-9 induced more harms than Gardasil, which could be explained by the fact that Gardasil 9 contains more of the AAHS aluminum adjuvant (500 micrograms of AAHS in Gardasil-9 vs. 225 micrograms of AAHS in Gardasil), and this dose-response relationship further corroborates the plausible claim that the AAHS aluminum adjuvant is a culprit in causing adverse events. *Id.*

15        281. Other researchers, including Tomljenovic and Shaw, who have closely looked into  
16      Gardasil, have opined that risks from the Gardasil vaccine seem to significantly outweigh the as yet  
17      unproven long-term benefits. In their view, vaccination is unjustified if the vaccine carries any  
18      substantial risk, let alone a risk of death, because healthy teenagers face an almost zero percent risk of  
19      death from cervical cancer.

**K. Merck has Concealed the Fact that Gardasil Increases the Risk of Fertility Problems**

282. Merck has never tested the impact of the Gardasil vaccines on human fertility.

23        283. Nevertheless, study volunteers reported devastating impacts on human fertility during  
24 combined trials, offering substantial evidence that the vaccine may be causing widespread impacts on  
25 human fertility, including increases in miscarriage, birth defects, premature ovarian failure, and  
26 premature menopause in girls and young women.

284. One of the serious adverse events now emerging in vaccinated girls, including teens, is  
28 premature ovarian failure. See, e.g., D. T. Little and H. R. Ward, *Adolescent Premature Ovarian*

1 *Insufficiency Following Human Papillomavirus Vaccination: A Case Series Seen in General Practice*,  
2 JOURNAL OF INVESTIGATIVE MEDICINE HIGH IMPACT, Case Reports 1-12 (Oct.-Dec. 2014); D. T. Little  
3 and H. R. Ward, *Premature ovarian failure 3 years after menarche in a 16-year-old girl following*  
4 *human papillomavirus vaccination*, BMJ CASE REPORTS (September 30, 2012).

5       285. Premature ovarian failure can occur after aluminum destroys the maturation process of  
6 the eggs in the ovaries.

7       286. Fertility has plummeted among American women following the 2006 mass introduction  
8 of the Gardasil vaccine. This is most evident in teen pregnancy statistics where numbers have more  
9 than halved since 2007.

10       287. The total fertility rate for the United States in 2017 continued to dip below what is  
11 needed for the population to replace itself, according to a report by the National Center of Health  
12 Statistics issued in January 2019, and the rate for women 15 to 44 fell another 2 percent between 2017  
13 and 2018.

14                   **L. There were an Increased Number of Deaths in the Gardasil Studies**

15       288. Merck's own preliminary studies predicted that Gardasil would kill and injure far more  
16 Americans than the HPV virus, prior to the introduction of the vaccine.

17       289. The average death rate in young women in the U.S. general population is 4.37 per  
18 10,000. See Brady E. Hamilton et al., "Births: Provisional Data for 2016," *Vital Statistics Rapid*  
19 *Release, Report No. 002*, June 2017.

20       290. The Gardasil pooled group had a death rate of 8.5 per 10,000, or almost double the  
21 background rate in the U.S.

22

23

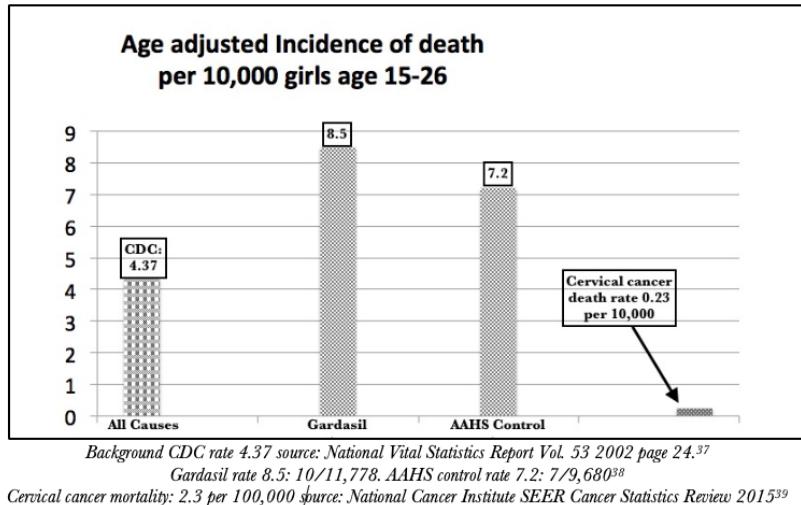
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291. When Merck added in deaths from belated clinical trials, the death rate jumped to 13.3 per 10,000 (21 deaths out of 15,706).

292. Merck dismissed all deaths as coincidences.

293. The total number of deaths was 21 in the HPV vaccine group and 19 in the comparator (AAHS) groups.

294. The death rate among vaccine recipients was 13.3 per 10,000, or 133 per 100,000 (21/15,706).

295. To put this in perspective, the death rate from cervical cancer in the United States is 2.3 per 100,000 women. This means that, according to Merck's own data, a girl is 58 times more likely to die from Gardasil than from cervical cancer.

#### **M. Post-Marketing Injuries -- The Raft of Injuries Seen in Merck's Clinical Trials Has Now Become A Population-Wide Chronic Disease Epidemic**

296. By 2010, reports coming in from all over the world linked the Gardasil vaccine to bizarre and troubling symptoms.

297. Many Gardasil survivors will have lifelong handicaps.

298. The severe adverse events from the Gardasil vaccination, seen since its widespread distribution, are similar to those injuries that Merck covered up during its clinical trials. They include autoimmune diseases, suicides, deaths, premature ovarian failures, reproductive problems, infertility, cervical cancer, sudden collapse, seizures, multiple sclerosis, strokes, heart palpitations, chronic

1 muscle pain, complex regional pain syndrome, and weakness.

2        299. Other frequently reported injuries include disturbances of consciousness; systemic pain  
3 including headache, myalgia, arthralgia, back pain and other pain; motor dysfunction, such as  
4 paralysis, muscular weightiness, and involuntary movements; numbness, and sensory disturbances;  
5 autonomic symptoms including hypotension, tachycardia, nausea, vomiting, and diarrhea; respiratory  
6 dysfunction, including dyspnea, and asthma; endocrine disorders, such as menstrual disorder and  
7 hypermenorrhea; and lastly, hypersensitivity to light, heart palpitations, migraine headaches,  
8 dizziness, cognitive deficits, personality changes, vision loss, joint aches, headaches, brain  
9 inflammation, chronic fatigue, death and severe juvenile rheumatoid arthritis.

10        300. The data show that Gardasil is yielding far more reports of adverse events than any  
11 other vaccine. For example, Gardasil had 8.5 times more emergency room visits, 12.5 times more  
12 hospitalizations, 10 times more life-threatening events, and 26.5 more disabilities than Menactra,  
13 another vaccine with an extremely high-risk profile.

14        301. As of December 2019, there have been more than 64,000 Gardasil adverse events  
15 reported to the FDA's Vaccine Adverse Event Reporting System ("VAERS") since 2006.

16        302. Moreover, studies have shown that only approximately 1 percent of adverse events are  
17 actually reported to FDA's voluntary reporting systems, thus, the true number of Gardasil adverse  
18 events in the United States may be as high as 6.4 million incidents.

19        303. The Vaccine Injury Compensation Program has paid out millions of dollars in damages  
20 for Gardasil-induced injuries and deaths.

21        304. The adverse events also include deaths. Parents, doctors, and scientists have reported  
22 hundreds of deaths from the Gardasil vaccine, post-marketing.

23        305. In order to conceal Gardasil's link to the deaths of teenagers, Merck has submitted  
24 fraudulent reports to VAERS, and posts fraudulent and misleading statements on its Worldwide  
25 Adverse Experience System.

26        306. For example, Merck attributed the death of a young woman from Maryland, Christina  
27 Tarsell, to a viral infection. Following years of litigation, a court determined that Gardasil caused  
28 Christina's death. There was no evidence of viral infection. Merck invented this story to deceive the

1 public about Gardasil's safety.

2       307. Merck submitted fraudulent information about Christina Tarsell's death to its  
3 Worldwide Adverse Experience System and lied to the FDA through the VAERS system. Merck  
4 claimed that Christina's gynecologist had told the company that her death was due to viral infection.  
5 Christina's gynecologist denied that she had ever given this information to Merck. To this day, Merck  
6 has refused to change its false entry on its own reporting system.

7                   **N. The Gardasil Vaccines' Harms Are Not Limited to the United States, Rather**  
8                   **the Vaccines Have Injured Patients All Over the World**

9       308. Gardasil is used widely in the international market. Widespread global experience has  
10 likewise confirmed that the vaccine causes serious adverse events with minimal proven benefit.

11       309. According to the World Health Organization's Adverse Event Databases, there have  
12 been more than 100,000 serious adverse events associated with Gardasil, outside the Americas. See  
13 WHO Vigibase database, keyword Gardasil: <http://www.vigiaccess.org>.

14                   **i. In Light of Gardasil's Serious and Debilitating Adverse Events, the**  
15                   **Japanese Government Rescinded Its Recommendation that Girls**  
16                   **Receive Gardasil**

17       310. In Japan, a country with a robust history of relative honesty about vaccine side effects,  
18 the cascade of Gardasil injuries became a public scandal.

19       311. Japan's health ministry discovered adverse events reported after Gardasil were many  
20 times higher than other vaccines on the recommended schedule. These included seizures, severe  
21 headaches, partial paralysis, and complex regional pain syndrome. See Hirokuni Beppu et al., *Lessons*  
22 *Learnt in Japan From Adverse Reactions to the HPV Vaccine: A Medical Ethics Perspective*, 2  
INDIAN J MED ETHICS 82 (April-June 2017).

23       312. Japanese researchers found that the adverse events rate of the HPV vaccine was as high  
24 as 9 percent, and that pregnant women injected with the vaccine aborted or miscarried 30 percent of  
25 their babies. See Ministry of Health, Labour and Welfare, Transcript "The Public Hearing on Adverse  
26 Events  
27 following HPV vaccine in Japan," February 26, 2014

28       313. The injuries caused the Japanese government to rescind its recommendation that girls

1 receive the HPV vaccine.

2       314. Japan withdrew its recommendation for Gardasil three months after it had added the  
3 vaccine to the immunization schedule, due to “an undeniable causal relationship between persistent  
4 pain and the vaccination.”

5       315. Uptake rates for the vaccine in Japan are now under 1 percent, compared to 53.7 percent  
6 fully vaccinated teenaged girls in the United States.

7       316. In late 2016 Japanese industry watchdog, MedWatcher Japan issued a scathing letter  
8 faulting the WHO for failing to acknowledge the growing body of scientific evidence demonstrating  
9 high risk of devastating side effects.

10      317. In 2015, the Japanese Association of Medical Sciences issued official guidelines for  
11 managing Gardasil injuries post-vaccination.

12      318. That same year, the Japanese Health Ministry published a list of medical institutions  
13 where staffs were especially trained to treat patients who had sustained Gardasil-induced injuries.

14      319. The Japanese government also launched a series of special clinics to evaluate and treat  
15 illnesses caused by the Gardasil vaccines.

16      320. The president of the Japanese Association of Medical Sciences stated that there was no  
17 proof that the vaccines prevent cancer.

18      321. These were developments that Merck was extremely anxious to suppress.

19      322. Merck hired the think tank, the Center for Strategic and International Studies (“CSIS”)  
20 and Professor Heidi Larson of the Vaccine Confidence Project in London, to assess the reasons for the  
21 Japanese situation. The overall conclusion was that the symptoms the girls were suffering from were  
22 psychogenic in nature and were a result of rumors spread online. In essence, Merck blamed the  
23 victims for the Gardasil-induced adverse events in Japan.

24                   **ii. Denmark Has Opened Specialized Clinics Specifically Focused on**  
25                   **Treating Gardasil-Induced Injuries, Including Gardasil-Induced**  
26                   **Autoimmune Diseases**

27      323. In March 2015, Denmark announced the opening of five new “HPV clinics” to treat  
28 children injured by Gardasil vaccines. Over 1,300 cases flooded the HPV clinics shortly after  
opening. See Zosia Chustecka, *Chronic Symptoms After HPV Vaccination: Danes Start Study*,

1 MEDSCAPE (November 13, 2015).

2

3                   **iii. Gardasil-Induced Adverse Events Caused the Government in**  
**Colombia to Conclude that Gardasil Would No Longer Be**  
**Mandatory**

4         324. In Colombia, more than 800 girls in the town of El Carmen de Bolivar reported  
5 reactions ranging from fainting to dizziness to paralysis in March of 2014, following vaccination with  
6 Gardasil.

7         325. With protests erupting across the country, the Colombian attorney general asked the  
8 Constitutional Court to rule on a lower court ruling on the outcome of a case of an injured girl.

9         326. In 2017, in response to an unresolved case, Colombia's constitutional court, ruled that  
10 the Colombian government could not infringe on the bodily integrity of its citizens. This decision  
11 meant that the government could not require the HPV vaccine to be mandatory.

12

13                   **iv. India Halted Gardasil Trials and Accused Merck of Corruption**  
**After the Death of Several Young Girls Who were Participants in the**  
**Trial**

14         327. Seven girls died in the Gardasil trials in India coordinated by Merck and the Gates  
15 Foundation. A report by the Indian Parliament accused the Gates Foundation and Merck of  
16 conducting “a well-planned scheme to commercially exploit” the nation’s poverty and powerlessness  
17 and lack of education in rural India in order to push Gardasil. *See 72<sup>nd</sup> Report on the Alleged*  
18 *Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Programme*  
19 *for Appropriate Technology in Health (PATH) in India* (August 2013).

20         328. The report alleges that Merck (through PATH, to whom it supplied vaccines) and the  
21 Gates Foundation resorted to subterfuge that jeopardized the health and well-being of thousands of  
22 vulnerable Indian children. The parliamentary report makes clear that the clinical trials could not have  
23 occurred without Merck corrupting India’s leading health organizations. *Id.*

24         329. The Report accused PATH, which was in collaboration with Merck, of lying to illiterate  
25 tribal girls to obtain informed consent, widespread forging of consent forms by Merck operatives,  
26 offering financial inducements to participate, and providing grossly inadequate information about  
27 potential risks. *Id.*

28         330. Many of the participants suffered adverse events including loss of menstrual cycles and

1 psychological changes like depression and anxiety. According to the report: PATH's "sole aim has to  
2 been to promote the commercial interests of HPV vaccine manufacturers, who would have reaped a  
3 windfall of profits had they been successful in getting the HPV vaccine included in the universal  
4 immunization program of the country... This [conduct] is a clear-cut violation of the human rights of  
5 these girls and adolescents." *Id.*

6        331. A 2013 article in the *South Asian Journal of Cancer* concludes that the HPV vaccine  
7 program is unjustifiable. “It would be far more productive to understand and strengthen the reasons  
8 behind the trend of decreasing cervical cancer rates than to expose an entire population to an uncertain  
9 intervention that has not been proven to prevent a single cervical cancer or cervical cancer death to  
10 date.” See Sudeep Gupta, *Is Human Papillomavirus Vaccination Likely to be a Useful Strategy in*  
11 *India?* 2 SOUTH ASIAN J CANCER 194 (October-December 2014).

12           332. The article goes on to say: "A healthy 16-year-old is at zero immediate risk of dying  
13 from cervical cancer, but is faced with a small, but real risk of death or serious disability from a  
14 vaccine that has yet to prevent a single case of cervical cancer... There is a genuine cause for concern  
15 regarding mass vaccination in this country." *Id.*

16           333. In April 2017, the Indian government blocked the Gates Foundation from further  
17 funding of the Public Health Foundation of India and other non-governmental organizations,  
18 effectively barring them from influencing India's national vaccine program. *See* Nida Najar, *India's*  
19 *Ban on Foreign Money for Health Group Hits Gates Foundation*, THE NEW YORK TIMES, April 20,  
20 2017.

## **O. Merck's Fraud Has Paid Off Handsomely Resulting in Over \$3 Billion in Gardasil Sales Annually**

22 334. Merck's corruption and fraud in researching, testing, labeling, and promoting Gardasil  
23 have paid off handsomely.

335. Presently, two doses of Gardasil 9 typically cost about \$450, plus the cost of two office visits

336 By comparison, the cost of the DTaP vaccine is about \$25 per dose.

27 337 The HPV vaccine is the most expensive vaccine on the market

<sup>28</sup> 338 Since approximately 1 in 42 000 American women die of cervical cancer annually, the

1 cost of avoiding a single death is over \$18 million, assuming the Gardasil vaccine is 100 percent  
2 effective.

3 339. In 2018, the Gardasil vaccines made \$2.2 billion for Merck in the U.S. alone.

4 340. In 2019, Merck made \$3.7 billion in worldwide revenues from the Gardasil vaccines.

5 341. Gardasil is Merck's most lucrative vaccine and its third-highest selling product.

6 342. Gardasil is crucial to Merck's overall financial health. Merck identifies Gardasil as one  
7 of its "key products," meaning that any change in Gardasil's cash flow affects the corporation as a  
8 whole.

9 343. Merck's 10-K financial reports note that, for example, the discovery of a previously  
10 unknown side effect, or the removal of Gardasil from the market, would hurt Merck's bottom line.

11 **III. Ashley America Sustained Serious Injuries, Including but Not Limited to Non-**  
12 **Epileptic Seizures, Likely Related to Autoimmune Dysregulation,**  
13 **Neurocardiogenic Syncope, Likely Related to Dysregulation of the Autonomic**  
**Nervous System Leading to Chronic Migraine Headaches and Dizziness as a Result**  
**of Her Gardasil Injections**

14 **A. Gardasil and Its Ingredients Caused Plaintiff's Injuries, Including but not Limited to,**  
15 **Non-Epileptic Seizures, Neurocardiogenic Syncope Related to Dysregulation of the**  
16 **Autonomic Nervous System, Chronic Fatigue Syndrome, and Resulting Sequalae,**  
**Causing Plaintiff to Suffer From Severe, Debilitating, Disabling and Painful Chronic**  
**Injuries**

17 344. Plaintiff was 18 years old when she received her first Gardasil vaccine on October 20,  
18 2014.

19 345. Plaintiff agreed to receive the Gardasil injections after she was exposed to marketing by  
20 Merck, that Gardasil is very safe, that Gardasil prevents cancer and that teenagers must get the  
21 Gardasil vaccine. Plaintiff relied upon Merck's ubiquitous representations concerning the safety and  
22 efficacy of the Gardasil vaccine in consenting to her Gardasil vaccination.

23 346. Prior to receiving her Gardasil injection, Plaintiff was in her usual state of health and  
24 enjoying her adolescence. Plaintiff was a senior in high school and excitedly looking forward to going  
25 off to college, as she had good grades and was active scholastically and participated in sporting  
26 activities.

27 347. On October 20, 2014, during a routine physical examination, Plaintiff's doctor at Best  
28 Care Family Medical in Barneveld, New York, recommended that Plaintiff receive the Gardasil

1 vaccine. Plaintiff's doctor informed her the Gardasil vaccine was a safe and effective vaccine for  
2 preventing cervical cancer. Her doctor further stated that if she did not receive the vaccine, she would  
3 be putting others in danger. In light of her doctor's recommendations, as well as Merck's relentless  
4 marketing and advertising messages, to which Plaintiff had been exposed to concerning the safety and  
5 efficacy of Gardasil, Plaintiff consented to be injected with the "cervical cancer vaccine," Gardasil.  
6 Immediately thereafter, on October 22, 2014, Plaintiff experienced extreme dizziness while at school  
7 and went to the nurse's office. While there, Plaintiff fainted and her school called Plaintiff's mother,  
8 who took Ashley to Faxton, St. Luke's Medical Center Emergency Center, where Plaintiff was  
9 diagnosed with Syncope of an unknown origin at that time. For the next several months, Plaintiff  
10 experienced syncope of unknown origin, suffering extreme headaches, and dizziness.

11       348. On November 6, 2014, following Plaintiff's referral to Mohawk Cardiology, in Utica,  
12 New York, she was fitted with a Holter monitor following a CT scan that day, with the hopes of  
13 finding an answer for Plaintiff's unexplained and suddenly arising condition. Plaintiff returned to  
14 Faxton at St. Luke's Medical Center and an MRI was scheduled on November 13, 2014. Plaintiff's  
15 Syncope was believed to be Neurocardiogenic in origin.

16       349. Plaintiff was monitored throughout November and December 2014. Plaintiff's  
17 cardiologist suggested that her family video record any fainting spells. In December, after observing  
18 video recordings and the data from the Holter, Plaintiff's cardiologist diagnosed Plaintiff with  
19 Complex Seizure Disorder. The Holter was returned to the cardiologist and Plaintiff did not suspect  
20 that the Gardasil vaccine possibly caused Plaintiff to experience seizures, syncope of an unknown  
21 origin at that time, migraines, dizziness, and other debilitating symptoms.

22       350. Unfortunately, Plaintiff's condition deteriorated into the following year, and in February  
23 2015, Plaintiff's primary care physician excused her attendance throughout her senior year of high  
24 school. Before receiving the Gardasil vaccine, Plaintiff was expected to graduate with honors, but  
25 after receiving the Gardasil vaccine, Plaintiff's grades dropped substantially.

26       351. Notwithstanding her condition, Plaintiff and her mother were informed it was important  
27 for Plaintiff to get her second Gardasil dosage, which she received on April 23, 2015. Plaintiff  
28 immediately experienced non-epileptic seizures following the second dosage. Her parents recorded

1 seizures on April 25, May 5, 16, 18 and 20, and June 29th. The neurocardiogenic syncope, migraines,  
2 dizziness, and non-epileptic seizures continues to the present time, all of which have caused Plaintiff  
3 to experience chronic fatigue syndrome, brain fog, depression, and anxiety. Plaintiff refused her third  
4 dosage of Gardasil.

5       352. As a result of her post-Gardasil symptoms, Plaintiff was unable to enroll in college in  
6 2015, and when she finally enrolled in the fall of 2016, she had a difficult time. Plaintiff did not pass  
7 most of her classes in her first semester of college, due to too many absences and her inability to  
8 timely complete her assignments because of her post-Gardasil symptoms. In 2017, she enrolled in the  
9 spring semester, but signed up for fewer classes to accommodate her condition. Plaintiff was forced  
10 to change her major from Biology – with aspirations of obtaining a Veterinarian Doctorate – to  
11 Business Administration, because she could not handle the course work due to her medical condition.  
12 For instance, during chemistry labs, Plaintiff would need an assistance with handling chemicals used  
13 during class because her medical condition caused her to have unsteady hands.

14       353. Based upon her chronic and severe post-Gardasil symptoms and adverse events as  
15 outlined above, and the tests performed by her medical providers, Plaintiff has been diagnosed with  
16 various medical conditions, including but not limited to non-epileptic seizures, likely related to  
17 autoimmune dysregulation, neurocardiogenic syncope believed to be related to dysregulation of the  
18 autonomic nervous system, chronic fatigue syndrome, chronic migraines, headaches, and dizziness,  
19 and resulting depression, anxiety, and brain fog all resulting from her Gardasil injections.

20       354. As previously discussed, the medical literature has documented other patients who, like  
21 Plaintiff, have suffered serious autonomic dysfunctions, and who experienced the same side effects as  
22 those Plaintiff has suffered, and who were diagnosed with Gardasil-induced autonomic diseases. See  
23 E. Israeli et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Darja Kanduc, *Quantifying the*  
24 *Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS  
25 AND ONCOLOGY 65 (2009); Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination*  
26 *with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Darja Kanduc, *Potential Cross-Reactivity*  
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28 THERAPEUTICS AND ONCOLOGY 159 (2011); Deirdre Little et al., *Premature ovarian failure 3 years*

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6 IN ALLERGY AND IMMUNOLOGY 152 (October 2013); Svetlana Blitshetyn, *Postural Tachycardia*  
7 *Syndrome Following Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135  
8 (2014); Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese*  
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11 *for Neurological Disease*, JOURNAL OF TOXICOLOGY (2014); Louise S. Brinth et al., *Orthostatic*  
12 *Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against*  
13 *Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-Lavin et al., *HPV Vaccination*  
14 *Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL RHEUMATOLOGY 1981 (2015); Louise S.  
15 Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic Encephalomyelitis a Relevant Diagnosis in*  
16 *Patients with Suspected Side Effects to Human Papilloma Virus Vaccine*, 1 INT. J. OF VACCINE &  
17 VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV*  
18 *Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Rebecca E. Chandler et al.,  
19 *Current Safety Concerns With Human Papillomavirus Vaccine: A Cluster Analysis of Reports in*  
20 *VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al., *Autonomic Dysfunction and HPV*  
21 *Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and Svetlana Blitshetyn, *Human*  
22 *Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions*, CLINICAL  
23 AUTONOMIC RESEARCH (2019); Lars Jørgensen et al., *Benefits and Harms of the Human*  
24 *Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical*  
25 *Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020).

26       355. Plaintiff contends that her Gardasil injection caused her to develop serious and  
27 debilitating injuries, including but not limited to, non-epileptic seizures, likely related to autoimmune  
28 dysregulation, currently diagnosed neurocardiogenic syncope, related to dysregulation of the

1 autonomic nervous system, chronic fatigue syndrome, chronic migraines, headaches, and dizziness,  
2 and resulting depression, anxiety, and brain fog, as well as a constellation of adverse symptoms,  
3 complications, injuries, and other adverse events, many of which are alleged herein and all of which  
4 were caused by Gardasil or otherwise linked to her Gardasil-induced autoimmune disorder.

5           **P. “It is Not Revolutions and Upheavals That Clear the Road to New and Better**  
6           **Days, But Revelations, Lavishness and Torments of Someone’s Soul, Inspired**  
7           **and Ablaze.” – Boris Pasternak, *After the Storm***

8       356. Pursuant to Section 300aa-11(a) of the National Vaccine Injury Compensation  
9 Program: “No person may bring a civil action for damages ..... against a vaccine administrator or  
10 manufacturer in a State or Federal court for damages arising from a vaccine-related injury ...  
11 associated with the administration of a vaccine ..... unless a petition has been filed, in accordance  
12 with section 300aa-16 of this title, for compensation under the Program for such injury ... and (I) the  
13 United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on  
14 such petition and (II) such person elects under section 300aa-21(a) to file such an action.” *See* 42  
15 U.S.C. §§ 300aa–11(a)(2)(A).

16       357. Title 42, Section 300aa-16 (c) further states: “If a petition is filed under section 300aa-  
17 11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be  
18 stayed with respect to a civil action brought for such injury or death for the period beginning on the  
19 date the Petition is filed and ending on the date...an election is made under section 300aa-21(a) of this  
title to file the civil action ...” *See* 42 U.S.C. §§ 300aa–16(c).

20       358. In full compliance with the aforementioned federal law, Plaintiff, duly filed her petition  
21 with the U.S. Court of Federal Claims seeking compensation for her Gardasil vaccine-related injuries  
22 under the National Vaccine Injury Compensation Program. An Order Concluding Proceedings was  
23 issued on April 14, 2022.

24       359. Having complied with National Vaccine Injury Compensation Program administrative  
25 procedure and having duly filed her election to proceed with a civil action, Plaintiff hereby timely  
26 initiates the instant action against Merck, the manufacturer and promoter of the Gardasil vaccines  
27 which caused her debilitating injuries. Through this civil action, Plaintiff seeks to hold Merck  
28 accountable for its negligent, reckless, and fraudulent conduct and she seeks full compensation from

1 Merck for the physical and emotional injuries and harms she sustained as a result of Gardasil.

2       360. Moreover, by engaging in conduct that Merck knew was unsafe and likely to injure  
3 patients and by placing Gardasil's profits ahead of patient safety, Merck has engaged in the same  
4 fraudulent, malicious and oppressive conduct it engaged in with respect to Vioxx. Plaintiff, therefore,  
5 requests that exemplary damages be assessed against Merck, so as to, once again, attempt to deter  
6 Merck and other would-be defendants from engaging in similar reprehensible conduct.

## **CAUSES OF ACTION**

## COUNT ONE

## NEGLIGENCE

10       361. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set  
11 forth herein and further alleges:

362. Merck is the researcher, manufacturer, labeler, and promoter of the Gardasil  
and the subsequent Gardasil 9 vaccines.

14       363. Merck marketed Gardasil to patients, including teenagers such as Plaintiff, her parents  
15 and her medical providers.

16       364. Merck had a duty to exercise reasonable care in the research, manufacture, marketing,  
17 advertisement, supply, promotion, packaging, sale, and distribution of Gardasil, including the duty to  
18 take all reasonable steps necessary to research, manufacture, label, promote and/or sell a product that  
19 was not unreasonably dangerous to consumers, users, and other persons coming into contact with the  
20 product.

21       365. At all times relevant to this litigation, Merck had a duty to exercise reasonable care in  
22 the marketing, advertising, and sale of Gardasil. Merck's duty of care owed to consumers and the  
23 general public included providing accurate, true, and correct information concerning the efficacy and  
24 risks of Gardasil and appropriate, complete, and accurate warnings concerning the potential adverse  
25 effects of Gardasil and its various ingredients and adjuvants.

366. At all times relevant to this litigation, Merck knew or, in the exercise of reasonable care,  
should have known of the hazards and dangers of Gardasil and specifically, the serious, debilitating  
and potentially fatal adverse events associated with Gardasil, including but not limited to autoimmune

1 diseases (including, but not limited to, POTS and OI), fibromyalgia, increased risk of cancer  
2 (including cervical cancer, which was the very cancer it was promoted as preventing) and death.

3       367. Accordingly, at all times relevant to this litigation, Merck knew or, in the exercise of  
4 reasonable care, should have known that use of Gardasil could cause Plaintiff's injuries and thus  
5 created a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

6       368. Merck knew or, in the exercise of reasonable care, should have known that its  
7 negligently and poorly designed clinical trials and studies were insufficient to test the true long-term  
8 safety and efficacy of Gardasil.

9       369. Merck also knew or, in the exercise of reasonable care, should have known that its  
10 targeted consumers and patients (who were pre-teen and teen children), the parents of these patients  
11 and the children's medical providers were unaware of the true risks and the magnitude of the risks  
12 associated with Gardasil and the disclosed and undisclosed ingredients of Gardasil.

13       370. As such, Merck breached its duty of reasonable care and failed to exercise ordinary care  
14 in the research, development, manufacturing, testing, marketing, supply, promotion, advertisement,  
15 packaging, labeling, sale, and distribution of Gardasil, in that Merck manufactured and produced a  
16 defective and ineffective vaccine, knew or had reason to know of the defects and inefficacies inherent  
17 in its products, knew or had reason to know that a patient's exposure to Gardasil created a significant  
18 risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of  
19 these defects, risks and injuries.

20       371. Merck failed to appropriately and adequately test the safety and efficacy of Gardasil and  
21 its individual ingredients and adjuvants.

22       372. Despite the ability and means to investigate, study, and test its products and to provide  
23 adequate warnings, Merck has failed to do so. Indeed, Merck has wrongfully concealed information  
24 and has further made false and/or misleading statements concerning the safety and efficacy of  
25 Gardasil.

26       373. Merck's negligence is outlined in detail in this Complaint, and included, among other  
27 things:

28           a)      Manufacturing, producing, promoting, creating, researching, labeling, selling,

1 and/or distributing Gardasil without thorough and adequate pre-and post-market  
2 testing and studies;

3 b) Manufacturing, producing, promoting, researching, labeling, selling, and/or  
4 distributing Gardasil while negligently and intentionally concealing and failing  
5 to accurately and adequately disclose the results of the trials, tests, and studies of  
6 Gardasil, and, consequently, the lack of efficacy and risk of serious harm  
7 associated with Gardasil;

8 c) Failing to undertake sufficient studies and conduct necessary tests to determine  
9 the safety of the ingredients and/or adjuvants contained within Gardasil, and the  
10 propensity of these ingredients to render Gardasil toxic, increase the toxicity of  
11 Gardasil, whether these ingredients are carcinogenic or associated with  
12 autoimmune diseases and other injuries;

13 d) Negligently designing and conducting its clinical trials so as to prevent the  
14 clinical trials from revealing the true risks, including but not limited to, long  
15 terms risks and risks of autoimmune diseases associated with Gardasil;

16 e) Negligently designing and conducting its clinical trials so as to mask the true  
17 risks, including but not limited to, long terms risks and risks of autoimmune  
18 diseases and cancers associated with Gardasil;

19 f) Failing to test Gardasil against a true inert placebo and lying to the public that  
20 Gardasil was tested against a placebo, when in reality, all, or nearly all, studies  
21 used a toxic placebo that included the aluminum adjuvant AAHS;

22 g) Failing to have a sufficient number of studies for the targeted patient population  
23 which included pre-teen girls (and boys) between the ages of nine and 12;

24 h) Not using the commercial dosage (and instead using a lower dosage of the  
25 adjuvant and ingredients) in one of the key clinical trials used to obtain licensing  
26 for the commercial dosage of Gardasil;

27 i) Using restrictive exclusionary criteria in the clinical study patient population  
28 (including for example, the exclusion of anyone who had prior abnormal Pap

1 tests, who had a history of immunological or nervous system disorders, or was  
2 allergic to aluminum or other ingredients), but then not revealing or warning  
3 about these exclusionary criteria in the label and knowing that, for most of these  
4 ingredients and allergies, there are limited resources for the public to test for  
5 such allergies in advance of being vaccinated;

6 j) Negligently designing and conducting its trials so as to create the illusion of  
7 efficacy when in reality the Gardasil Vaccines *have not* been shown to be  
8 effective against preventing cervical and anal cancer;

9 k) Failing to use reasonable and prudent care in the research, manufacture, labeling  
10 and development of Gardasil so as to avoid the risk of serious harm associated  
11 with the prevalent use of Gardasil;

12 l) Failing to provide adequate instructions, guidelines, warnings, and safety  
13 precautions to those persons who Merck could reasonably foresee would use  
14 and/or be exposed to Gardasil;

15 m) Failing to disclose to Plaintiff and her medical providers and to the general  
16 public that Gardasil is ineffective when used in patients who have previously  
17 been exposed to HPV, and also failing to disclose that Gardasil actually  
18 increases the risk of cervical cancer, including in any child or patient who has  
19 previously been exposed to HPV;

20 n) Failing to disclose to Plaintiff and her medical providers and to the general  
21 public that use of and exposure to Gardasil presents severe risks of cancer  
22 (including cervical cancer, the very cancer it is promoted as preventing), fertility  
23 problems, autoimmune diseases and other grave illnesses as alleged herein;

24 o) Failing to disclose to Plaintiff and her medical providers and to the general  
25 public that use of and exposure to Gardasil presents severe risks of triggering  
26 and increasing the risk of various autoimmune diseases, including but not  
27 limited to POTS and OI;

28 p) Failing to disclose to Plaintiff, her parents, her medical providers and to the

1 general public that, contrary to Merck's promotion of the vaccine, Gardasil has  
2 not been shown to be effective at preventing cervical cancer and that the safest  
3 and most effective means of monitoring and combating cervical cancer is  
4 regular testing, including Pap tests;

5 q) Representing that Gardasil was safe and effective for its intended use when, in  
6 fact, Merck knew or should have known the vaccine was not safe and not  
7 effective for its intended use;

8 r) Falsely advertising, marketing, and recommending the use of Gardasil, while  
9 concealing and failing to disclose or warn of the dangers Merck knew to be  
10 associated with or caused by the use of Gardasil;

11 s) Falsely promoting Gardasil as preventing cervical cancer when Merck knows  
12 that it has not done any studies to demonstrate that Gardasil prevents cervical  
13 cancer and, indeed, its clinical studies revealed that Gardasil actually increases  
14 the risk of cervical cancer;

15 t) Engaging in false advertising and disease mongering by scaring parents and  
16 children into believing that cervical and anal cancer is far more prevalent than it  
17 really is; that all cervical and anal cancer was linked to HPV; that Gardasil  
18 prevented cervical and anal cancer, when in reality none of these representations  
19 were true as cervical cancer rates were declining in the United States due to Pap  
20 testing and Gardasil has not been shown to prevent against all strains of HPV  
21 that are associated with cervical and anal cancer and, indeed, it has never been  
22 shown to prevent cervical and anal cancer;

23 u) Failing to disclose all of the ingredients in Gardasil, including but not limited to  
24 the fact that Gardasil contains dangerous HPV L1-DNA fragments and that  
25 these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist –  
26 further adjuvanting the vaccine and making it more potent and dangerous;

27 v) Declining to make any changes to Gardasil's labeling or other promotional  
28 materials that would alert consumers and the general public of the true risks and

1                   defects of Gardasil;

2       w)     Systemically suppressing or downplaying contrary evidence about the risks,

3                   incidence, and prevalence of the side effects of the Gardasil Vaccines by, inter

4                   alia, orchestrating the retraction of peer-reviewed and published studies and

5                   vilifying and attempting to ruin the careers of any scientists who openly question

6                   Gardasil's safety and efficacy.

7       374.   Merck knew and/or should have known that it was foreseeable that patients, such as

8 Plaintiff, would suffer injuries as a result of Merck's failure to exercise ordinary care in the

9 manufacturing, marketing, labeling, distribution, and sale of Gardasil.

10      375.   Plaintiff and upon information and belief, her medical providers, did not know the true

11 nature and extent of the injuries that could result from the intended use of and/or exposure to Gardasil

12 or its adjuvants and ingredients.

13      376.   Merck's negligence was the proximate cause of the injuries, harm, and economic losses

14 that Plaintiff suffered, and will continue to suffer, as described herein.

15      377.   Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or

16 had Merck via its labeling, advertisements and promotions provided adequate and truthful warnings

17 and properly disclosed and disseminated the true risks, limitations and lack of efficacy associated with

18 Gardasil to medical providers, patients and the public, then upon information and belief, Plaintiff's

19 medical providers would not have offered or recommended Gardasil to Plaintiff. Moreover, even if

20 after Merck's dissemination of truthful information concerning the true risks and efficacy limitation of

21 Gardasil, Plaintiff's medical providers had offered Gardasil, then upon information and belief, the

22 providers would have heeded any warnings issued by Merck and relayed to Plaintiff the safety risks

23 and efficacy limitations that Merck should have warned them about, but failed to do so. Had Plaintiff

24 been informed of the true risks and efficacy limitation concerning Gardasil, either through her medical

25 providers or through Merck's ubiquitous direct-to-consumer promotional marketing, then Plaintiff

26 would have consented to Plaintiff being injected with Gardasil.

27      378.   As a proximate result of Merck's wrongful acts and omissions and its negligent and

28 fraudulent testing, labeling, manufacturing, marketing and promotion of Gardasil, Plaintiff has

1 suffered and continues to suffer severe and permanent physical injuries and associated symptomology  
2 and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also  
3 has a substantial fear of suffering additional and ongoing harms, including but not limited to now  
4 being at an increased risk of cancer and future symptoms and harms associated with her autoimmune  
5 disease and other injuries caused by Gardasil.

6       379.     As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has  
7 suffered and continues to suffer economic losses, including considerable financial expenses for  
8 medical care and treatment, and diminished income capacity, and she will continue to incur these  
9 losses and expenses in the future.

10       380. Merck's conduct, as described above, was aggravated, oppressive, fraudulent, and  
11 malicious. Merck regularly risks the lives of teenagers, including Plaintiff, with full knowledge of the  
12 limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made  
13 conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her  
14 medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue  
15 appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant  
16 harm to children and patients who were being injected with Gardasil, and therefore warrants an award  
17 of punitive damages.

18       381. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for  
19 compensatory and punitive damages, together with interest, and costs herein incurred, and all such  
20 other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the  
21 issues contained herein.

## COUNT TWO

## **STRICT LIABILITY**

## **(FAILURE TO WARN)**

25       382. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set  
26 forth herein, and further alleges:

27 383. Plaintiff brings this strict liability claim against Merck for failure to warn.

28 384. At all times relevant to this litigation, Merck engaged in the business of researching,

1 testing, manufacturing, marketing, selling, distributing, and promoting Gardasil, which is defective  
2 and unreasonably dangerous to consumers, including Plaintiff, because it does not contain adequate  
3 warnings or instructions concerning the dangerous characteristics of Gardasil and its ingredients and  
4 adjuvants. These actions were under the ultimate control and supervision of Merck.

5       385. Merck researched, tested, manufactured, inspected, labeled, distributed, marketed,  
6 promoted, sold, and otherwise released into the stream of commerce Gardasil, and in the course of  
7 same, directly advertised or marketed the vaccine to consumers and end users, including Plaintiff and  
8 her medical providers, and Merck therefore had a duty to warn of the risks associated with the  
9 reasonably foreseeable uses of Gardasil and a duty to instruct on the proper,  
10 safe use of these products.

11       386. At all times relevant to this litigation, Merck had a duty to properly research, test,  
12 develop, manufacture, inspect, package, label, market, promote, sell, distribute, provide proper  
13 warnings, and take such steps as necessary to ensure that Gardasil did not cause users and consumers  
14 to suffer from unreasonable and dangerous risks. Merck had a continuing duty to instruct on the  
15 proper, safe use of these products. Merck, as manufacturer, seller, or distributor of vaccines, is held to  
16 the knowledge of an expert in the field.

17       387. At the time of manufacture, Merck could have provided warnings or instructions  
18 regarding the full and complete risks of Gardasil because it knew or should have known of the  
19 unreasonable risks of harm associated with the use of and/or exposure to these products.

20       388. At all times relevant to this litigation, Merck failed to properly investigate, study,  
21 research, test, manufacture, label or promote Gardasil. Merck also failed to minimize the dangers to  
22 children, patients, and consumers of Gardasil products and to those who would foreseeably use or be  
23 harmed by Gardasil, including Plaintiff.

24       389. Despite the fact that Merck knew or should have known that Gardasil posed a grave and  
25 unreasonable risk of harm (including but not limited to increased risk of autoimmune disease, and the  
26 various other Gardasil induced injuries that Plaintiff has sustained, it failed to warn of the risks  
27 associated with Gardasil. The dangerous propensities of Gardasil and the carcinogenic characteristics  
28 and autoimmune-inducing characteristics of Gardasil, as described in this Complaint, were known to

1 Merck, or scientifically knowable to Merck through appropriate research and testing by known  
2 methods, at the time it distributed, supplied, or sold Gardasil, and not known to end users and  
3 consumers, such as Plaintiff and her medical providers.

4       390. Merck knew or should have known that Gardasil and its ingredients and adjuvants  
5 created significant risks of serious bodily harm to children and patients, as alleged herein, and Merck  
6 failed to adequately warn patients, parents, medical providers and reasonably foreseeable users of the  
7 risks and lack of efficacy of Gardasil. Merck has wrongfully concealed information concerning  
8 Gardasil's dangerous nature and lack of efficacy and has further made false and misleading statements  
9 concerning the safety and efficacy of Gardasil.

10       391. Plaintiff was injected with Gardasil in its intended or reasonably foreseeable manner  
11 without knowledge of its unreasonable dangerous and ineffectual characteristics.

12       392. Plaintiff could not have reasonably discovered the defects and risks associated with  
13 Gardasil before or at the time of her injections. Plaintiff relied upon the skill, superior knowledge,  
14 and judgment of Merck.

15       393. Merck knew or should have known that the warnings disseminated with Gardasil were  
16 inadequate, and failed to communicate adequate information concerning the true risks and lack of  
17 efficacy of Gardasil and failed to communicate warnings and instructions that were appropriate and  
18 adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses,  
19 including injection in teenagers.

20       394. The information that Merck did provide or communicate failed to contain relevant  
21 warnings, hazards, and precautions that would have enabled patients, parents of patients and the  
22 medical providers of patients to properly utilize, recommend or consent to the utilization of Gardasil.  
23 Instead, Merck disseminated information that was inaccurate, false, and misleading and which failed  
24 to communicate accurately or adequately the lack of efficacy, comparative severity, duration, and  
25 extent of the serious risk of injuries associated with Gardasil; continued to aggressively promote the  
26 efficacy and safety of its products, even after it knew or should have known of Gardasil's  
27 unreasonable risks and lack of efficacy; and concealed, downplayed, or otherwise suppressed, through  
28 aggressive marketing and promotion, any information or research about the risks, defects and dangers

1 of Gardasil.

2       395. To this day, Merck has failed to adequately and accurately warn of the true risks of  
3 Plaintiff's injuries, including but not limited to, POTS, neuropathy, dysautonomia, and autoimmune  
4 diseases, associated with the use of and exposure to Gardasil, and has failed to warn of the additional  
5 risks that Plaintiff is now exposed to, including, but not limited to, the increased risk of cancer and  
6 other potential side effects and ailments.

7       396. As a result of Merck's failure to warn and false promotion, Gardasil is and was  
8 defective and unreasonably dangerous when it left the possession and/or control of Merck, was  
9 distributed by Merck, and used by Plaintiff.

10       397. Merck is liable to Plaintiff for injuries caused by its failure, as described above, to  
11 provide adequate warnings or other clinically relevant information and data regarding Gardasil, the  
12 lack of efficacy and serious risks associated with Gardasil and its ingredients and adjuvants.

13       398. The defects in Merck's Gardasil vaccine were substantial and contributing factors in  
14 causing Plaintiff's injuries, and, but for Merck's misconduct and omissions and Gardasil's defects,  
15 including its defective labeling and false promotion, Plaintiff would not have sustained her injuries  
16 which she has sustained to date, and would not have been exposed to the additional prospective risk  
17 and dangers that are associated with Gardasil.

18       399. Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or  
19 had Merck, via its labeling, advertisements, and promotions provided adequate and truthful warnings  
20 and properly disclosed and disseminated the true risks, limitations, and lack of efficacy associated  
21 with Gardasil to medical providers, patients, and the public, then upon information and belief,  
22 Plaintiff's medical providers would not have offered or recommended Gardasil to Plaintiff.  
23 Moreover, even if after Merck's dissemination of truthful information concerning the true risks and  
24 efficacy limitation of Gardasil, Plaintiff's medical providers had offered Gardasil, then upon  
25 information and belief, the providers would have heeded any warnings issued by Merck and relayed to  
26 Plaintiff the safety risks and efficacy limitations that Merck should have warned them about, but  
27 failed to do so. Had Plaintiff been informed of the true risks and efficacy limitation concerning  
28 Gardasil, either through her medical providers or through Merck's ubiquitous direct-to-consumer

1 promotional marketing, then Plaintiff would not have consented to Plaintiff being injected with  
2 Gardasil.

3       400. As a proximate result of Merck's wrongful acts and omissions and its negligent and  
4 fraudulent testing, labeling, manufacturing, marketing and promotion of Gardasil, Plaintiff has  
5 suffered and continues to suffer severe and permanent physical injuries and associated symptomology  
6 and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also  
7 has a substantial fear of suffering additional and ongoing harms, including but not limited to now  
8 being at an increased risk of cancer and future symptoms and harms associated with her autoimmune  
9 disease and other injuries caused by Gardasil.

10      401. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has  
11 suffered and continues to suffer economic losses, including considerable financial expenses for  
12 medical care and treatment, and diminished income capacity, and she will continue to incur these  
13 losses and expenses in the future.

14      402. Merck's conduct, as described above, was oppressive, fraudulent, and malicious.  
15 Merck regularly risks the lives of teenagers, including Plaintiff, with full knowledge of the limited  
16 efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made  
17 conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her  
18 medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue  
19 appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant  
20 harm to children, teenagers, and patients who were being injected with Gardasil, and therefore  
21 warrants an award of punitive damages.

22      403. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for  
23 compensatory and punitive damages, together with interest, and costs herein incurred, and all such  
24 other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the  
25 issues contained herein.

26 \\

27 \\

28 \\

# **COUNT THREE**

## **STRICT LIABILITY**

### **(MANUFACTURING DEFECT)**

4 404. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set  
5 forth herein, and further alleges:

6 405. Plaintiff brings this strict liability claim against Merck for manufacturing defect.

7       406. At all times relevant to this litigation, Merck engaged in the business of researching,  
8 testing, developing, manufacturing, marketing, selling, distributing, and promoting Gardasil, which is  
9 defective and unreasonably dangerous to consumers, including Plaintiff, because of manufacturing  
10 defects, which patients, including Plaintiff and her medical providers did not expect.

11       407. Upon information and belief, the Gardasil vaccines injected into Plaintiff were defective  
12 and unreasonably dangerous because they failed to comply with manufacturing specifications required  
13 by the governing manufacturing protocols and also required by the regulatory agencies, including but  
14 not limited to the FDA, by among other things, containing ingredients and toxins that were not  
15 disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert.

16       408. Upon information and belief, and as way of example, the Gardasil injected into Plaintiff  
17 was defective and unreasonably dangerous because it failed to comply with the approved  
18 manufacturing specifications, by containing dangerous and undisclosed HPV L1-DNA fragments, and  
19 these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist, further adjuvanting the  
20 vaccine and making it more potent and dangerous than intended.

21       409. Upon information and belief, and as way of example, the Gardasil injected into Plaintiff  
22 was defective and unreasonably dangerous because it failed to comply with the approved  
23 manufacturing specifications, by containing dangerous and undisclosed ingredients and neurotoxins,  
24 including but not limited to, phenylmethylsulfonyl fluoride (PMSF), a toxic nerve agent that is not  
25 intended for human consumption or injection.

26       410. Plaintiff was injected with Gardasil in its intended or reasonably foreseeable manner  
27 without knowledge of its dangerous and ineffectual characteristics.

411. Plaintiff and her medical providers could not reasonably have discovered the defects.

1 including the manufacturing defects, and risks associated with Gardasil before or at the time of her  
2 injections. Plaintiff relied upon the skill, superior knowledge, and judgment of Merck.

3       412. Merck is liable to Plaintiff for injuries caused as a result of its manufacturing defects.

4       413. The defects in Merck's Gardasil vaccine were substantial and contributing factors in  
5 causing Plaintiff's injuries, and, but for Merck's misconduct and omissions and Gardasil's defects,  
6 including but not limited to its manufacturing defects, Plaintiff would not have sustained the injuries  
7 she has sustained to date, and would not have been exposed to the additional prospective risk and  
8 dangers associated with Gardasil.

9       414. As a proximate result of Merck's wrongful acts and Gardasil's manufacturing defects,  
10 Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated  
11 symptomology and has suffered severe and permanent emotional injuries, including pain and  
12 suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but  
13 not limited to now being at an increased risk of cancer and future symptoms and harms associated  
14 with her autoimmune disease and other injuries caused by Gardasil.

15       415. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered  
16 and continues to suffer economic losses, including considerable financial expenses for medical care  
17 and treatment, and diminished income capacity, and she will continue to incur these losses and  
18 expenses in the future.

19       416. Merck's conduct, as described above, was oppressive, fraudulent, and malicious.  
20 Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the limited  
21 efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made  
22 conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff, and her  
23 medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue  
24 appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant  
25 harm to children and patients who were being injected with Gardasil, and therefore warrants an award  
26 of punitive damages.

27       417. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for  
28 compensatory and punitive damages, together with interest, and costs herein incurred, and all such

1 other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the  
2 issues contained herein.

3 **COUNT FOUR**

4 **BREACH OF EXPRESS WARRANTY**

5 418. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set  
6 forth herein, and further alleges:

7 419. Merck engaged in the business of testing, researching, manufacturing, labeling,  
8 marketing, selling, distributing, and promoting Gardasil, which is defective and unreasonably  
9 dangerous to consumers, including Plaintiff.

10 420. At all times relevant to this litigation, Merck expressly represented and warranted  
11 through statements made in its Gardasil label, publications, television advertisements, billboards, print  
12 advertisements, online advertisements and website, and other written materials intended for  
13 consumers, patients, parents of minor-aged patients, medical providers, and the general public, that  
14 Gardasil was safe and effective at preventing cancer. Merck advertised, labeled, marketed, and  
15 promoted Gardasil, representing the quality to consumers, patients, medical providers and the public  
16 in such a way as to induce their purchase or use, thereby making an express warranty that Gardasil  
17 would conform to the representations.

18 421. These express representations included incomplete warnings and instructions that  
19 purport, but fail, to include the complete array of risks associated with Gardasil. Merck knew and/or  
20 should have known that the risks expressly included in Gardasil's promotional material and labels did  
21 not and do not accurately or adequately set forth the risks of developing the serious injuries  
22 complained of herein. Nevertheless, Merck falsely and expressly represented that Gardasil was "safe"  
23 for use by individuals such as Plaintiff, and/or that Gardasil was "effective" in preventing cancer and  
24 that anyone who was vaccinated with Gardasil would be "one less" person with cancer.

25 422. The representations about Gardasil, as set forth herein, contained or constituted  
26 affirmations of fact or promises made by the seller to the buyer, which related to the goods and  
27 became part of the basis of the bargain, creating an express warranty that the goods would conform to  
28 the representations.

1       423. Merck breached these warranties because, among other things, Gardasil is ineffective at  
2 preventing cancer, defective, dangerous, unfit for use, and is associated with a myriad of dangerous  
3 and undisclosed risks, including, but not limited to, the risk of autoimmune disease, including POTS,  
4 the risk of developing cervical cancer in women (even though Merck promoted it as preventing  
5 cervical cancer), and the risk of fertility problems for young girls. Specifically, Merck breached the  
6 warranties in the following ways:

- 7           a) Representing to patients and the medical community, including Plaintiff and/or  
8 her medical providers that Gardasil is effective in preventing cancer, including  
9 cervical and anal cancer, when Merck knew that contrary to these  
10 representations (i) no clinical studies were performed to test if Gardasil prevents  
11 cancer; (ii) the clinical studies confirmed that Gardasil is indeed ineffective  
12 when used in patients who have previously been exposed to HPV, and that  
13 Gardasil actually increases the risk of cancer a patient who has been previously  
14 exposed to HPV; and (iii) there are safer and more effective methods of  
15 monitoring for and attempting to prevent cervical or anal cancer, including but  
16 not limited to regular testing, such as regular Pap smears for cervical cancer, and  
17 monitoring for anal cancer.
- 18           b) Representing to patients and the medical community, including Plaintiff and her  
19 medical providers that Gardasil is safe, when in reality, Gardasil causes and  
20 presents serious risks of cancer, autoimmune disease, including but not limited  
21 to POTS, and other grave illnesses as outlined herein;
- 22           c) Engaging in false advertising and disease mongering by scaring parents and  
23 teenagers into believing that cervical and anal cancer is far more prevalent than  
24 it really is; that all cervical anal cancer was linked to HPV; that Gardasil  
25 prevented cervical cancer, when in reality none of these representations were  
26 true as cervical cancer rates were declining in the United States due to Pap  
27 testing and Gardasil has not been shown to prevent against all strains of HPV  
28 that are associated with cervical cancer and indeed it has never been shown to

1 prevent cervical or anal cancer.

2 424. Merck had sole access to material facts concerning the nature of the risks and defects  
3 associated with Gardasil as expressly stated within its promotional material and labels, and Merck  
4 knew that patients and users such as Plaintiff could not have reasonably discovered the truth about the  
5 inefficacies and serious risks associated with Gardasil as alleged herein.

6 425. Plaintiff had no knowledge of the falsity or incompleteness of Merck's statements and  
7 representations concerning Gardasil.

8 426. Plaintiff was exposed to the ubiquitous promotional material and representations Merck  
9 made in its direct-to-consumer advertisements and marketing materials concerning the safety and  
10 efficacy of Gardasil, including: that Gardasil prevents cervical and anal cancer and these cancers are  
11 prevalent (even though children rarely get cervical or anal cancer and Pap tests are the best frontline  
12 defense in detecting and fighting cervical cancer); that "good mothers" vaccinate their children and  
13 that Gardasil is perfectly safe. However, had Merck in these advertisements not engaged in disease  
14 mongering and deception, but instead had informed her the truth about the serious risks of Gardasil (as  
15 outlined in this Complaint) and its lack of efficacy, she would never have consented to being injected  
16 with Gardasil, nor would Plaintiff have consented to any of the Gardasil injections had she been  
17 adequately informed about the questionable efficacy and serious risks associated with Gardasil.

18 427. As a proximate result of Merck's wrongful acts and it breaches of warranties  
19 concerning the safety and efficacy of Gardasil, Plaintiff has suffered and continues to suffer severe  
20 and permanent physical injuries, and associated symptomology, and has suffered severe and  
21 permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of  
22 suffering additional and ongoing harms, including but not limited to now being at an increased risk of  
23 cancer, and future symptoms and harms associated with her autoimmune disease and other injuries  
24 caused by Gardasil.

25 428. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has  
26 suffered and continues to suffer economic losses, including considerable financial expenses for  
27 medical care and treatment, and diminished income capacity, and she will continue to incur these  
28 losses and expenses in the future.

1           429. Merck's conduct, as described above, was oppressive, fraudulent, and malicious.  
2 Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the limited  
3 efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made  
4 conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her  
5 medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue  
6 appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant  
7 harm to children and patients who were being injected with Gardasil, and therefore warrants an award  
8 of punitive damages.

9       430. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for  
10 compensatory and punitive damages, together with interest, and costs herein incurred, and all such  
11 other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the  
12 issues contained herein.

## COUNT FIVE

## **COMMON LAW FRAUD**

15       431. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set  
16 forth herein, and further alleges:

17 432. Merck is the researcher, manufacturer, labeler, and promoter of Gardasil.

18 433. Merck marketed Gardasil to and for the benefit of patients, including teenagers such as  
19 Plaintiff and her medical providers.

20        434. Merck had a duty to deal honestly and truthfully with regulators, patients, consumers  
21 and medical providers in its development, testing, marketing, promotion, and sale of Gardasil.

435. Merck's duty of care owed to patients and medical providers included providing  
436 accurate, complete, true, and correct information concerning the efficacy and risks of Gardasil in its  
437 direct-to-consumer advertisements, promotional material, and labeling.

436. At all times relevant to this litigation, Merck knew or should have known of the hazards  
and dangers of Gardasil and specifically, the serious, debilitating and potentially fatal adverse events  
associated with Gardasil, including but not limited to autoimmune diseases, increased risk of cancer,  
and death.

1       437. At all times relevant to this litigation, Merck knew or should have known that its poorly  
2 designed clinical trials and studies were insufficient to test the true long-term safety and efficacy of  
3 Gardasil.

4       438. At all times relevant to this litigation, Merck expressly represented through statements it  
5 made in its publications, ubiquitous television advertisements, billboards, print advertisements, online  
6 advertisements and website, and other written materials intended for consumers, patients, parents of  
7 minor-aged patients, medical providers, and the general public, that Gardasil was safe and effective at  
8 preventing cancer.

9       439. These express representations included incomplete warnings and instructions that  
10 purport, but fail, to include the complete array of risks associated with Gardasil. By way of example  
11 Merck's marketing material, including its "One Less" television and print advertisement campaign  
12 (including but not limited to Gardasil posters in medical facilities and doctors' offices), which  
13 Plaintiff had been exposed to, stated that Gardasil was safe, that Gardasil was effective in preventing  
14 cancer, that Gardasil was a "cervical cancer vaccine," and that any child or teenager who was  
15 vaccinated with Gardasil would lead to "one less" person with cervical or anal cancer. The only safety  
16 warnings Merck provided in these marketing materials was that a patient could get pain, swelling or  
17 redness at injection site, fever, and/or nausea.

18       440. The ubiquitous nature of these Gardasil commercials and the Gardasil marketing  
19 campaign gave the impression that cervical cancer was on the rise and more prevalent than it actually  
20 was, and that all good mothers vaccinate their children with the "cervical cancer vaccine."

21       441. Merck knew or should have known that the risks expressly included in Gardasil's  
22 promotional material and labels did not and do not accurately or adequately set forth the true and  
23 complete risks of developing the serious injuries that are associated with Gardasil, as previously  
24 alleged herein, and which include but are not limited to, POTS, systemic adverse events, autoimmune  
25 disease, increased risk of cancer, and death.

26       442. The same promises of efficacy and limited and incomplete warnings Merck relayed in  
27 its direct-to-consumer advertising, were what Plaintiff's medical providers relayed to her when they  
28 recommended Gardasil – i.e., that if Plaintiff got vaccinated with Gardasil, it will prevent her from

1 getting cervical cancer, and the only risks associated with Gardasil are temporary dizziness, soreness,  
2 redness, minor pain, and itching at the injection site.

3       443. Plaintiff had been exposed to Merck's marketing material concerning Gardasil,  
4 including the aforementioned "One Less" marketing campaign and other print advertisements and  
5 posters at doctors' offices, and the representations made by Merck therein that Gardasil is effective at  
6 preventing cervical and anal cancer, that Gardasil is safe and that its only side-effects are essentially  
7 minor injection site pain and swelling and the possible onset of a fever or nausea. Prior to providing  
8 consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was never informed by Merck, or  
9 anyone else, that Gardasil is linked to a host of serious debilitating and chronic adverse events  
10 including, autoimmune diseases (including, but not limited to, POTS), increased risk of cancer, and  
11 death.

12       444. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was  
13 never informed by Merck, or anyone else, that Merck had not conducted the proper testing necessary  
14 to demonstrate the efficacy and full safety of Gardasil.

15       445. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was  
16 never informed by Merck, or anyone else, that Merck had, as alleged herein, manipulated its clinical  
17 studies to mask and conceal the adverse events associated with Gardasil.

18       446. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was  
19 never informed by Merck, or anyone else, that the Gardasil clinical trials never established that  
20 Gardasil can prevent cervical or anal cancer, even though Merck in its promotional material to which  
21 Plaintiff had been exposed, falsely represented that Gardasil was a "cervical cancer vaccine" and that  
22 a patient who received Gardasil would result in "one less" woman getting cervical cancer.

23       447. Merck's representations were false, because in truth, Gardasil has not been proven to  
24 prevent cervical or anal cancer and is associated with a myriad of dangerous and undisclosed risks,  
25 including, but not limited to, the risk of autoimmune disease, including POTS, the increased risk of  
26 cancer, and other serious side effects. The false representations Merck made to the patients, children,  
27 teenagers, the parents of children and teenagers, the medical community, including to Plaintiff,  
28 included:

1                   a) that Gardasil is effective in preventing cervical and anal cancer, when Merck  
2                   knew that, contrary to these representations (i) no clinical studies were  
3                   performed to test whether Gardasil prevents cancer; and (ii) the clinical studies  
4                   confirmed that Gardasil is indeed ineffective when used in patients who have  
5                   previously been exposed to HPV, and that Gardasil actually increases the risk of  
6                   cervical cancer in any child or patient who has been previously exposed to HPV;  
7                   b) that Gardasil is safe, when in reality, Gardasil causes and presents severe risks  
8                   of cancer (including cervical cancer, the very cancer it is promoted as  
9                   preventing), fertility problems, autoimmune disease, including POTS, OI and  
10                  other grave illnesses;  
11                  c) false advertising and disease mongering by scaring parents into believing that  
12                  cervical and anal cancer was far more prevalent than it really was; that Gardasil  
13                  prevented cervical and anal cancer; and that Gardasil only had risks of injection  
14                  site pain and fever, when in reality none of these representations were true as  
15                  cervical cancer rates were declining in the United States due to Pap testing and  
16                  Gardasil has not been shown to prevent cervical or anal cancer and indeed some  
17                  studies demonstrated that it actually increased the risk of cervical cancer; and  
18                  Gardasil was linked to a host of serious, chronic and sometimes fatal diseases,  
19                  including autoimmune diseases, as previously outlined in this Complaint.

20                  448. These representations and other similar representations were made by Merck to the  
21                  public, including to Plaintiff, with the intent that parents would either seek out Gardasil from their  
22                  medical providers or otherwise would provide their consent when they were offered Gardasil.

23                  449. At the time they provided their consent to the Gardasil injection, Plaintiff was not aware  
24                  of the falsity of Merck's aforementioned representations concerning the safety and efficacy of  
25                  Gardasil.

26                  450. Plaintiff reasonably and justifiably relied upon the truth of the assurance made by  
27                  Merck in its direct-to-consumer marketing concerning the efficacy and safety of Gardasil (which were  
28                  also echoed by Plaintiff's medical providers), when Plaintiff provided her consent to Plaintiff being

1 injected with the Gardasil vaccine.

2       451. Had Merck's advertisements and promotional material, which Merck targeted to  
3 teenagers and the parents of teenagers, and which Plaintiff received and on which she relied, provided  
4 complete and truthful warnings and properly disclosed and disseminated the true risks, limitations and  
5 lack of efficacy associated with Gardasil, then Plaintiff would not have consented to being injected  
6 with Gardasil.

7       452. Merck also engaged in a number of additional fraudulent activities that led to regulators,  
8 medical providers (upon information and belief, including but not limited Plaintiff's medical  
9 providers), and the general public (including directly and/or indirectly Plaintiff) to be duped into  
10 believing that Gardasil is safe and effective. These fraudulent acts are outlined in greater detail in the  
11 preceding paragraphs of this Complaint, and included, among others:

- 12           a) Failing to test Gardasil against a true inert placebo and lying to the public that  
13                   Gardasil was tested against a placebo, when in reality, all, or nearly all, studies  
14                   used a toxic placebo that included the dangerous aluminum adjuvant AAHS.
- 15           b) Failing to conduct a sufficient number of studies for the targeted patient  
16                   population which included pre-teen girls (and boys) between the ages of nine  
17                   and 12.
- 18           c) Not using the commercial dosage (and instead using a lower dosage of the  
19                   adjuvant and ingredients) in one of the key clinical trials, which was used to  
20                   obtain licensing for the commercial dosage of Gardasil;
- 21           d) Using very restrictive exclusionary criteria in the clinical study patient  
22                   population (including for example, exclusion of anyone who had prior abnormal  
23                   Pap tests, who had a history of immunological or nervous system disorders or  
24                   was allergic to aluminum or other ingredients), but then not revealing or  
25                   warning about these exclusionary criteria in the label and knowing that for most  
26                   of these ingredients and allergies, there are limited resources for the public to  
27                   test for such allergies in advance of being vaccinated;
- 28           e) Failing to disclose all of the ingredients in Gardasil, including but not limited to

the fact that Gardasil contains dangerous HPV L1-DNA fragments and that these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist – further adjuvanting the vaccine and making it more potent and dangerous.

453. Merck engaged in the above mentioned fraudulent conduct as well as the additional fraudulent conduct detailed throughout this Complaint with the intent to enhance Gardasil's safety and efficacy profile and to conceal Gardasil's serious risks and efficacy shortcomings in order to secure regulatory approval and more importantly, so as to encourage physicians and medical providers to recommend Gardasil to patients and to prepare and encourage patients to request and consent to Gardasil injections.

454. Plaintiff could not reasonably have discovered the falsity of Merck's representations, the fraudulent nature of Merck's conduct, and the defects and risks associated with Gardasil before or at the time of her injections. Plaintiff relied upon the skill, superior knowledge, and judgment of Merck, the manufacturer, labeler, and promoter of Gardasil, and they detrimentally relied upon Merck's fraudulent, false, and misleading statements, omissions, and conduct.

15        455. As a proximate result of Merck's fraudulent, false, and misleading statements,  
16 omissions, and conduct concerning the safety and efficacy of Gardasil, Plaintiff has suffered and  
17 continues to suffer severe and permanent physical injuries and associated symptomology and has  
18 suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a  
19 substantial fear of suffering additional and ongoing harms, including but not limited to now being at  
20 an increased risk of cancer and future symptoms and harms associated with her autoimmune disease  
21 and other injuries caused by Gardasil.

22       456. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has  
23 suffered and continues to suffer economic losses, including considerable financial expenses for  
24 medical care and treatment, and diminished income capacity, and he will continue to incur these  
25 losses and expenses in the future.

26 457. Merck's conduct, as described above, was oppressive, fraudulent, and malicious.  
27 Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the limited  
28 efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made

conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

6       458. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for  
7 compensatory and punitive damages, together with interest, and costs herein incurred, and all such  
8 other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the  
9 issues contained herein.

## **PRAYER FOR RELIEF**

11 WHEREFORE, Plaintiff, Ashley America, requests that the Court enter judgment in her favor  
12 and against Merck & Co., Inc., and Merck, Sharp and Dohme Corporation (collectively “Merck”) as  
13 to all causes of action, and awarding as follows:

- A. For compensatory damages, in an amount exceeding this Court's jurisdictional minimum and to be proven at trial;
- B. For economic and non-economic damages in an amount to be proven at trial;
- C. For medical, incidental, hospital, psychological and other expenses in an amount to be proven at trial;
- D. For loss of earnings and earnings capacity, in an amount to be proven at trial;
- E. For an award of pre-judgment and post-judgment interest as provided by law;
- F. For exemplary and punitive damages against Merck;
- G. For preliminary and/or permanent injunctive relief against Merck;
- H. For an award providing for payment of reasonable fees, court costs, and other litigation expenses as permitted by law;
- I. For such other and further relief as this Honorable Court may deem just and proper.

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